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(71) Applicant: VIACOR, INC. [US/US]; 260-B Fordham Road, Wilmington, MA 01887 (US).

(72) Inventors: WOOLFSON, Steven, B.; Constitution Marina, 28, Constitution Road, P.O. Box 51837, Boston, MA 02205 (US). STREETER, Richard, B.; 66 Brookside Avenue, Winchester, MA 01890 (US). TAYLOR, Daniel, C.; 35 Faneuil Street, Brighton, MA 02135 (US). COHN, William, E.; 104 Lagrange Street, Chestnut Hill, MA 02467 (US).

(74) Agent: PANDISCIO, Mark, J.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

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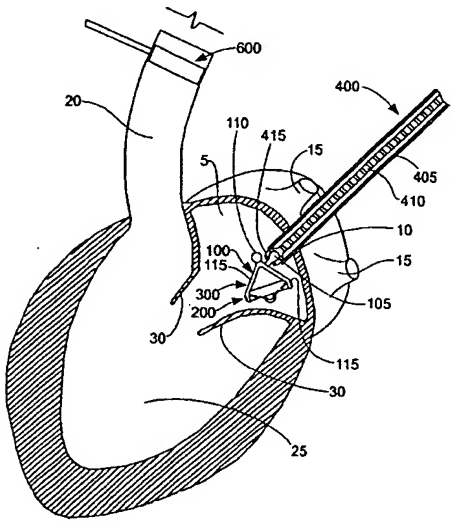
(54) Title: METHOD AND APPARATUS FOR RESECTING AND REPLACING AN AORTIC VALVE



(57) Abstract: Apparatus for resecting a diseased heart valve, the apparatus comprising: a body portion having a first end and a second end in opposition to one another, a lateral wall extending from the first end to the second end, the lateral wall defining an inner surface and an outer surface in opposition to one another, the inner surface and the outer surface defining arcuate surfaces, respectively, and the body portion defining a longitudinal axis from the first end to the second end; a first handle and a second handle attached to the body portion to extend from the first end thereof and the second end thereof, respectively; a cutting blade selectively rotatable about the longitudinal axis and disposed adjacent to the inner surface of the body portion; a set of retaining arms positionably mounted between the second handle and the second end of the body portion, the set of retaining arms being selectively positionable from a contracted state to an expanded state, the contracted state forming a first diameter having a first width in a direction perpendicular to the longitudinal axis of the body portion, the expanded state forming a second diameter having a second width in a direction perpendicular to the longitudinal axis of the body portion; the second width being larger than a first width of the first diameter in the direction perpendicular to the longitudinal axis of the body portion; a pass-off tool having a proximal end and a distal end, a first attachment device at the distal end thereof, the first attachment device configured to selectively engage the first handle attached to the body portion so as to allow placement of the second handle of the body portion adjacent to the diseased heart valve; and a controller tool having a proximal end and a distal end, a second attachment device at the distal end thereof, the second attachment device configured to selectively engage the second handle attached to the body portion so as to allow positioning of the second end of the body portion adjacent to the diseased heart valve, a cutting blade actuator configured to cause the cutting blade to selectively rotate relative to the longitudinal axis of the body portion, and a retaining arm actuator configured to selectively position the set of retaining arms from the contracted state to the expanded state.

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METHOD AND APPARATUS FOR RESECTING AND REPLACING AN AORTIC VALVE

Reference To Pending Prior Patent Applications

This patent application:

(1) is a continuation-in-part of pending prior U.S. Patent Application Serial No. 09/896,259, filed 06/29/01 by John R. Liddicoat et al. for METHOD AND APPARATUS FOR PERFORMING A PROCEDURE ON A CARDIAC VALVE (Attorney's Docket No. VIA-7);

(2) claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/373,042, filed 04/16/2002 by Steven B. Woolfson et al. for METHOD AND APPARATUS FOR RESECTING AND REPLACING AN AORTIC VALVE (Attorney's Docket No. VIA-27 PROV), and

(3) claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/425,891, filed 11/13/2002 by William E. Cohn for METHOD AND APPARATUS FOR RESECTING AND REPLACING AN AORTIC VALVE (Attorney's Docket No. VIA-42 PROV).

The three above-identified patent applications are hereby incorporated by reference.

Field Of The Invention

This invention relates to apparatus and methods for performing cardiac surgery in general, and more particularly to apparatus and methods for performing cardiac surgery while the heart is beating.

Background Of The Invention

Of all valvular heart lesions, aortic stenosis carries the worst prognosis. Within one year of diagnosis, approximately half of all patients with critical aortic stenosis have died, and by three years, this figure rises to approximately 80%. Currently, the most prominent and effective treatment for patients with aortic stenosis is aortic valve replacement via open heart surgery. Unfortunately, this procedure is a substantial and invasive undertaking for the patient.

While there have been significant advances in heart valve technology over the past 30 years, there has been little progress in the development of safer and less invasive valve delivery systems. Aortic valve replacement currently requires a sternotomy or thoracotomy, use of cardiopulmonary bypass to arrest the heart and lungs, and a large incision on the aorta. The native valve is resected through this incision and then a prosthetic valve is sutured to the inner surface of the aorta with a multitude of sutures passing only partly into the wall of the aorta. Given the current invasiveness of this procedure and the requirement to utilize cardiopulmonary bypass, aortic valve replacement surgery is associated with a high risk of morbidity and mortality. This is especially true in elderly patients, and in those patients who require concomitant coronary artery bypass grafting. Even when a good surgical result is achieved, virtually all patients require approximately 6 weeks to several months to fully recover from the procedure. In order to decrease these associated risks of aortic

valve surgery, many have pursued novel approaches and technologies.

Less invasive approaches to aortic valve surgery have generally followed two paths.

In the 1980's, there was a flurry of interest in percutaneous balloon valvotomy. In this procedure, a cardiologist introduced a catheter through the femoral artery to dilate the patient's aortic valve, thereby relieving the stenosis. Using the technology available at that time, success was limited: the valve area was increased only minimally, and nearly all patients had restenosis within one year.

More recently, surgeons have approached the aortic valve via smaller chest wall incisions. However, these approaches still require cardiopulmonary bypass and cardiac arrest, which themselves entail significant morbidity and a prolonged post-operative recovery.

The ideal minimally invasive approach to the treatment of aortic valve disease requires aortic valve replacement without cardiopulmonary bypass and

without cardiac arrest. Such an approach would greatly reduce patient morbidity and mortality and hasten recovery. Unfortunately, although there has been great progress in the treatment of coronary artery disease without cardiopulmonary bypass (e.g., angioplasty, with or without stenting, and "off-pump" coronary artery bypass grafting), similar advances have not yet been realized in heart valve surgery. With an aging population and improved access to advanced diagnostic testing, the incidence and accurate diagnosis of aortic stenosis will continue to increase. The development of a system for "off-pump" aortic valve replacement would be of significant benefit to this increasing patient population.

There are three important challenges to replacing a diseased aortic valve without cardiopulmonary bypass.

The first challenge is to remove the diseased valve without causing stroke or other ischemic events that might result from the liberation of particulate material while removing the diseased valve.

The second challenge is to prevent cardiac failure during removal of the diseased valve. In this respect it must be appreciated that the aortic valve continues to serve a critical function even when it is diseased. However, as the diseased valve is removed, it becomes acutely and severely incompetent, causing the patient to develop heart failure which results in death unless the function of the valve is taken over by another means.

The third challenge is placing a prosthetic valve into the vascular system and affixing it to the wall of the aorta. More particularly, during cardiac rhythm, the aortic and arterial pressures are substantially greater than atmospheric pressure. Therefore, any sizable incision made to the aorta in order to insert a standard valve prosthesis into the arterial system creates the potential for uncontrollable bleeding from the incision site. Furthermore, even if bleeding is successfully controlled, pressures within the aorta may result in weakening of the aorta caused by aortic wall

dissection. In addition, large incisions on the aorta also increase the potential for liberating plaque from the aortic wall that can lead to embolic complications.

For these reasons, prior art valve prostheses potentially suitable for off-pump implantation have relied upon relatively flimsy expandable structures to support and secure the valve within the aorta. More particularly, these prosthetic valves are constructed so that they can be compressed to a relatively small dimension suitable for insertion into the arterial system, advanced to the site of the aortic valve, and then expanded against the aortic wall. Unfortunately, however, none of these relatively flimsy valve prostheses have proven adequate to endure the repetitive stresses undergone by the aortic valve over the ten to twenty years typically required.

In addition to the foregoing, the precise placement of such expandable prosthetic valves in the correct sub-coronary position can be extremely challenging, particularly in view of the high

pressure, pulsatile blood flow passing through the aorta. Furthermore, expandable prosthetic valves would typically be positioned from a remote artery, which would reduce the ability to precisely control the placement and positioning of the device and therefore would increases the risk of obstructing the coronary arteries. The expandable prosthetic valves are held on the ends of elongate, flexible catheters that are threaded into the aorta, around the aortic arch and then expanded. The pulsatile flow during cardiac rhythm induces a to-and-fro motion of the valve prosthesis relative to the aorta that makes the timing of valve expansion critical for proper placement of the expandable prosthetic valve and hence the survival of the patient.

Finally, many of the challenges discussed in the foregoing section pertaining to aortic valve replacement are also relevant to other procedures in the aortic root such as aortic valve resection, aortic valve decalcification, stent grafting for aortic dissections, etc.

Summary Of The Invention

It is, therefore, one object of the present invention to enable the passage of a device from the left atrium, through the left ventricle, and into the arterial system.

Further, another object of the present invention is to enable the implantation of a device in the arterial system without cardiopulmonary bypass.

Further, another object of the present invention is to enable the implantation of a prosthetic valve in the arterial system without cardiopulmonary bypass.

Another object of the present invention is to allow the insertion of such a valve while minimizing the risks to the patient posed by large arterial incisions.

And another object of the present invention is to simplify the precise placement of such a valve.

Further, another object of the present invention is to enable the implantation of a device other than a valve, such as but not limited to a valve resection

tool, a decalcifying tool, an aortic valve repair tool, or a stented aortic graft, in the arterial system without cardiopulmonary bypass.

Another object of the present invention is to allow the insertion of a device other than a valve, such as but not limited to a valve resection tool, a decalcifying tool, an aortic valve repair tool, or a stented aortic graft, while minimizing the risks to the patient posed by large arterial incisions.

And another object of the present invention is to simplify the precise placement of a device other than a valve, such as but not limited to a valve resection tool, a decalcifying tool, an aortic valve repair tool, or a stented aortic graft.

The present invention relates to a method and apparatus for positioning a device in the arterial system. More specifically, the present invention relates to a method and apparatus for positioning an aortic valve prosthesis in the aorta or aortic outflow tract, with or without cardiopulmonary bypass.

One aspect of the present invention is a method for deploying an aortic valve prosthesis. This valve prosthesis may include any of the known aortic valves including, but not limited to, stented and unstented bioprosthetic valves, stented mechanical valves, and expandable or self-expanding valves, whether biological or artificial.

In one aspect of the invention, there is provided a method of inserting a prosthesis or device from a lower pressure region into a higher pressure region of the cardiovascular system comprising the steps of: making an opening in a wall of a lower pressure region of the cardiovascular system; advancing the prosthesis or device through the opening and into the lower pressure region; and advancing the prosthesis or device through a natural barrier between the lower pressure region and the higher pressure region.

In another aspect of the invention, there is provided a method of inserting a prosthesis or device into a vessel within the arterial system comprising the steps of: making an opening in a wall of a low

pressure region of the heart; advancing the prosthesis or device through the opening and into the low pressure region; advancing the prosthesis or device through a natural barrier between the low pressure region and the left ventricle; and advancing the prosthesis or device from the left ventricle into the arterial system and the vessel.

And in another aspect of the invention, there is provided a method of inserting a prosthesis or device into a vessel within the arterial system comprising the steps of: making an opening in a wall of the left atrium; advancing the prosthesis or device through the opening and into the left atrium; advancing the prosthesis or device through the mitral valve and into the left ventricle; and advancing the prosthesis or device from the left ventricle into the arterial system and the vessel.

And in another aspect of the present invention, there is provided a method for positioning a device in the arterial system comprising the steps of: making a first opening leading to the left atrium; passing a

valve prosthesis through the first opening and into a cardiac chamber of the left side of the heart using a first manipulation instrument; making a second opening in the arterial system and advancing one end of a second manipulation instrument through the second opening and into the aforementioned cardiac chamber; securing the second manipulation instrument to the valve prosthesis; and then using the second manipulation instrument to retract at least some portion of the valve prosthesis out of the aforementioned cardiac chamber.

An alternative method for positioning a device in the arterial system comprises the steps of: making an opening leading to the left atrium; passing a valve prosthesis through the opening and into a cardiac chamber of the left side of the heart using an articulating manipulation instrument; using the articulating manipulation instrument to guide the valve prosthesis into the arterial cardiac chamber; releasing the valve prosthesis into a desired position: and then retracting at least a portion of

the articulating manipulation instrument out of the aforementioned cardiac chamber and left atrium.

The pressure of blood flowing through the left atrium is very low, peaking at a few inches of water during the cardiac cycle. This pressure is a small fraction of that found within the arterial system and thus permits insertion of a conventional valve prosthesis through a relatively large opening formed in the wall of the left atrium without the risk of uncontrollable bleeding. In this respect it will be appreciated that various methods are known to those skilled in the art for controlling bleeding from an incision into the left atrium. The left atrium also rarely suffers from atherosclerotic plaque formation or calcification, thus minimizing the risk of embolic debris during such incision.

Another aspect of the present invention is the use of a prosthesis holding apparatus for releasably holding the valve prosthesis during manipulation to its implant site. The prosthesis holding apparatus may be secured to the prosthetic valve at any suitable

location(s) through the use of any of a variety of approaches including, but not limited to, suture loops, barbs, hooks, grasping jaws, opposing magnetic poles, friction fits and the like. The prosthesis holding apparatus is configured to provide first and second manipulation mounts for engagement by the aforementioned first and second manipulation instruments, respectively, whereby the prosthetic valve can be delivered to its implant site. This construction is highly advantageous in that it permits the valve prosthesis to be passed easily and reliably from the first manipulation instrument to the second manipulation instrument within the vascular system.

In an alternative preferred embodiment, the prosthetic holding apparatus is attached on the ventricular side of the prosthesis. The aforementioned first manipulation instrument would articulate at or near the prosthetic valve to facilitate manipulation of the prosthesis holding apparatus (and hence the prosthesis itself) through the smallest possible incision site, then through the

left atrium, the mitral valve and within the heart to align and position the prosthesis within the aortic annulus or left ventricular outflow track. In this alternative embodiment, there is no need for the aforementioned second manipulation instrument or the second manipulation mount.

In addition, if the prosthesis holding apparatus is attached on the aortic side of the prosthesis, the manipulation instrument may articulate and may be introduced into the arterial system, brought across the mitral valve into the left atrium, out the left atrium to pick up the prosthesis holding apparatus (and hence the prosthesis) and then retracted back to position the prosthesis directly into the aortic annulus without the need for another manipulation instrument.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a first frame member and a second frame member configured in opposition to one another;

a cutting edge configured on the first frame member;

an adjustable connector positionably joining the first frame member to the second frame member, the adjustable connector configured to selectively position the first frame member and the second frame member between a first position and a second position, wherein the first frame member and the second frame member are positioned apart from one another in the first position so as to allow at least a portion of the diseased heart valve therebetween, and the first frame member and the second frame member are positioned together in the second position so as to cut the at least a portion of the diseased heart valve therebetween with the cutting blade so as to resect the diseased heart valve;

an actuator configured in operable connection to the adjustable connector, the actuator configurable to selectively position the adjustable connector between the first position and the second position; and

a first screen portion and a second screen portion disposed on the first frame portion and the second frame portion, respectively, the first screen portion and the second screen portion configured to allow blood flow through first frame member and second frame member and to contain the at least a portion of the diseased heart valve between the first frame member and the second frame member.

In another form of the present invention, there is provided a method of resecting a diseased heart valve, the method comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a first frame member and a second frame member configured in opposition to one another;

a cutting edge configured on the first frame member;

an adjustable connector positionably joining the first frame member to the second frame member, the adjustable connector configured to selectively position the first frame member and the second frame

member between a first position and a second position, wherein the first frame member and the second frame member are positioned apart from one another in the first position so as to allow at least a portion of the diseased heart valve therebetween, and the first frame member and the second frame member are positioned together in the second position so as to cut the at least a portion of the diseased heart valve therebetween with the cutting blade so as to resect the diseased heart valve;

an actuator configured in operable connection to the adjustable connector, the actuator configurable to selectively position the adjustable connector between the first position and the second position; and

a first screen portion and a second screen portion disposed on the first frame portion and the second frame portion, respectively, the first screen portion and the second screen portion configured to allow blood flow through first frame member and second frame member and to contain the at least a portion of

the diseased heart valve between the first frame member and the second frame member;

positioning the first frame member and the second frame member on opposed sides of the diseased heart valve, with the first frame member and the second frame member in the first position;

closing the first frame member and the second frame member from the first position to the second position by manipulating the actuator in operable connection to the adjustable connector so as to move the cutting edge through the at least a portion of the diseased heart valve; and

removing from a patient the first frame member and the second frame member closed together in the second position, with the at least a portion of the diseased heart valve therebetween.

In another form of the present invention, there is provided a method of resecting a diseased heart valve, the method comprising:

positioning a first frame member and a second frame member on opposed sides of the diseased heart

valve, with the first frame member and the second frame member positioned apart from one another;

closing the first frame member and the second frame member toward one another so as to pass a cutting edge disposed on the first frame member through at least a portion of the diseased heart valve; and

removing from the patient the first frame member and the second frame member closed together, with the at least a portion of the diseased heart valve therebetween.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a power shaver having a proximal end and a distal end, the power shaver defining a longitudinal axis from the proximal end to the distal end, and a cutting element disposed adjacent to the distal end of the power shaver; and

a power shaver guide having a first end and a second end in opposition to one another, the power

shaver guide defining a first opening extending into the first end, the first opening defining a first axis from the first end of the power shaver guide to the second end of the power shaver guide, the first opening configured to receive a portion of the power shaver therein, the power shaver guide having a given width from the first opening to an outer surface in a direction perpendicular to the first axis, the given width of the power shaver guide configured to prevent the wall of a cardiovascular structure from being cut by the power shaver disposed within the first opening and to permit the power shaver to be placed within the diseased valve.

In another form of the present invention, there is provided a method for resecting a diseased heart valve comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a power shaver having a proximal end and a distal end, the power shaver defining a longitudinal axis from the proximal end to the distal end, and a

cutting element disposed adjacent to the distal end of the power shaver; and

a power shaver guide having a first end and a second end in opposition to one another, the power shaver guide defining a first opening extending into the first end, the first opening defining a first axis from the first end of the power shaver guide to the second end of the power shaver guide, the first opening configured to receive a portion of the power shaver therein, the power shaver guide having a given width from the first opening to an outer surface in a direction perpendicular to the first axis, the given width of the power shaver guide configured to prevent the wall of a cardiovascular structure from being cut by the power shaver disposed within the first opening and to permit the power shaver to be placed within the diseased valve;

positioning the power shaver within the power shaving guide;

positioning the power shaver and power shaving guide through a cardiovascular structure to the diseased heart valve; and

cutting the diseased valve with the cutting element of the power shaver so as to resect the diseased heart valve.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a set of at least three expandable arms having a proximal end and a distal end in opposition to one another, the set of expandable arms defining a longitudinal axis from the proximal end to the distal end;

a first restraining element and a second restraining element configured at the proximal end of the set of expandable arms and the distal end of the set of at least three expandable arms, respectively, the first restraining element and the second restraining element configured to selectively position the set of at least three expandable arms between a

first position and a second position, the set of at least three expandable arms having a given width in a perpendicular direction to the longitudinal axis at the first position and having a larger width in the perpendicular direction to the longitudinal axis at the second position; and

a cutting device disposed on at least one of the at least three expandable arms, the cutting device configured to cut through the diseased heart valve.

In another form of the present invention, there is provided a method for resecting a diseased heart valve, the apparatus comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a set of at least three expandable arms having a proximal end and a distal end in opposition to one another, the set of expandable arms defining a longitudinal axis from the proximal end to the distal end;

a first restraining element and a second restraining element configured at the proximal end of

the set of expandable arms and the distal end of the set of at least three expandable arms, respectively, the first restraining element and the second restraining element configured to selectively position the set of at least three expandable arms between a first position and a second position, the set of at least three expandable arms having a given width in the perpendicular direction to the longitudinal axis at the first position and having a larger width in the perpendicular direction to the longitudinal axis at the second position; and

a cutting device disposed on at least one of the at least three expandable arms, the cutting device configured to cut through the diseased heart valve;

positioning the set of at least three expandable arms adjacent to the diseased heart valve;

expanding the set of at least three expandable arms from the first position to the second position; and

cutting the diseased heart valve with the cutting device disposed on the at least one of the at least three expandable arms.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a first frame member and a second frame member configured in opposition to one another;

a cutting edge configured on the first frame member;

an adjustable connector positionably joining the first frame member to the second frame member, the adjustable connector configured to selectively position the first frame member and the second frame member between a first position and a second position, wherein the first frame member and the second frame member are positioned apart from one another in the first position so as to allow at least a portion of the diseased heart valve therebetween, and the first frame member and the second frame member are positioned together in the second position so as to

cut the at least a portion of the diseased heart valve therebetween with the cutting blade so as to resect the diseased heart valve;

an actuator configured in operable connection to the adjustable connector, the actuator configurable to selectively position the adjustable connector between the first position and the second position; and

at least two spikes extending from the first frame member toward the second frame member, the at least two spikes being configured to pierce and secure leaflets of the diseased heart valve as the first frame member and the second frame member are positioned toward one another.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a catheter having a proximal end and a distal end, the catheter defining a longitudinal axis from the proximal end to the distal end; and

a set of blades positionably configurable at the distal end of the catheter, a hinge mechanism holding

the distal end of the set of blades together, and a control rod extending from the proximal end of the blades into the catheter, the control rod being configured to selectively position the set of blades from a first position within the catheter to a second position outside of the distal end of the catheter, to selectively expand the set of blades from a narrow width for disposition within the catheter to a wide width for cutting portions of the diseased heart valve with the set of blades, and to rotate the set of blades with respect to the longitudinal axis of the catheter.

In another form of the present invention, there is provided a method of resecting a diseased heart valve, the method comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a catheter having a proximal end and a distal end, the catheter defining a longitudinal axis from the proximal end to the distal end; and

a set of blades positionably configurable at the distal end of the catheter, a hinge mechanism holding the distal end of the set of blades together, and a control rod extending from the proximal end of the blades into the catheter, the control rod being configured to selectively position the set of blades from a first position within the catheter to a second position outside of the distal end of the catheter, to selectively expand the set of blades from a narrow width for disposition within the catheter to a wide width for cutting portions of the diseased heart valve with the set of blades, and to rotate the set of blades with respect to the longitudinal axis of the catheter;

placing distal end of the catheter adjacent to the diseased heart valve;

positioning the set of blades from the first position within the catheter to the second position outside of the distal end of the catheter;

expanding the set of blades from the narrow width for disposition within the catheter to the wide width

for cutting portions of the diseased heart valve with the set of blades; and

rotating the set of blades with respect to the longitudinal axis of the catheter so as to cut through the diseased heart valve.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a catheter having a proximal end and a distal end, and the catheter defining a longitudinal axis from the proximal end to the distal end;

a control rod having a proximal end and a distal end, the control rod being selectively positionable through the catheter and being selectively rotatable with respect to the longitudinal axis of the catheter;

an outer shell portion having a first edge and a second edge in opposition to one another, the outer shell portion having an inwardly facing side and an outwardly facing side in opposition to one another, the first edge of the outer shell portion being attached to the control rod along a surface thereof

parallel to the longitudinal axis of the catheter, and the outer shell portion adapted to be wound around the control rod; and

a spring having a first end and a second end, the first end of the spring being attached to the inwardly facing side of the outer shell portion adjacent to the second edge thereof, and the spring being disposed against the inwardly facing side of the outer shell portion;

wherein rotation of the control rod in a first direction in combination with a force applied by the spring contracts the outer shell portion toward the control rod so as to reduce a maximum outer diameter of the outer shell in a given direction perpendicular to the longitudinal axis of the catheter, and rotation of the control rod in a second direction in combination with the force applied by the spring rolls the outer shell portion away from the control rod so as to expand the maximum outer diameter of the outer shell portion in the given direction perpendicular to the longitudinal axis of the catheter.

In another form of the present invention, there is provided a method for resecting a diseased heart valve, the method comprising:

providing apparatus for resecting a diseased heart valve, the apparatus comprising:

a catheter having a proximal end and a distal end, and the catheter defining a longitudinal axis from the proximal end to the distal end;

a control rod having a proximal end and a distal end, the control rod being selectively positionable through the catheter and being selectively rotatable with respect to the longitudinal axis of the catheter;

an outer shell portion having a first edge and a second edge in opposition to one another, the outer shell portion having an inwardly facing side and an outwardly facing side in opposition to one another, the first edge of the outer shell portion being attached to the control rod along a surface thereof parallel to the longitudinal axis of the catheter, and

the outer shell portion adapted to be wound around the control rod; and

a spring having a first end and a second end, the first end of the spring being attached to the inwardly facing side of the outer shell portion adjacent to the second edge thereof, and the spring being disposed against the inwardly facing side of the outer shell portion;

positioning the distal end of the catheter adjacent to the diseased heart valve;

rotating the control rod in the second direction so as to expand the outer shell portion; and

withdrawing the apparatus from the human body.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a tubular body having a proximal end and a distal end, the tubular body defining a longitudinal axis from the proximal end to the distal end; and

an auger blade disposed within the tubular body and configured to selectively rotate with respect to the longitudinal axis of the tubular body;

the tubular body defining an opening configured therein so as to allow portions of the diseased heart valve therein, and the opening defining a junction region at a location where the auger blade contacts the tubular body and cuts the portions carried by the auger blade thereto.

In another form of the present invention, there is provided a method for resecting a diseased heart valve, the method comprising:

positioning an opening of a tubular body adjacent to the diseased heart valve; and

cutting the diseased heart valve with an auger blade rotating within the tubular body.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

an inner rod having a proximal end and a distal end, the inner rod defining a longitudinal axis from

the proximal end to the distal end, and the inner rod defining a first opening and a second opening in a lateral side thereof between the proximal end and the distal end;

a first outer shell and a second outer shell each having a selectively configurable length through the first opening and the second opening of the inner rod, respectively, the first outer shell and the second outer shell configured to be radially expandable depending on the length of the first outer shell and the second outer shell configured through the first opening and the second opening, respectively; and

a blade extending between the first outer shell and the second outer shell, the blade being radially expandable away from the inner rod together with the first outer shell.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

an inner cylinder having an outer tube rotatably disposed thereto, the inner cylinder and outer tube

having a distal end and a proximal end, and the inner cylinder defining a longitudinal axis from the distal end to the proximal end;

at least one barb extending away from the distal end of the inner cylinder; and

three blades pivotally attached to the distal end of the outer tube, the three blades being selectively configurable in a first position and a second position, the first position configured with the blades closed toward one another so as to cover the at least one barb and provide a narrow cross-section therethrough in a perpendicular direction to the longitudinal axis, and a second position configured with the blades opened away from one another so as to expose the at least one barb and provide a cutting diameter having a greater cross-section therethrough than the narrow cross-section in the perpendicular direction to the longitudinal axis;

wherein the three blades are positioned closed toward one another through a body to a location adjacent to a diseased heart valve, the three blades

are opened away from one another so as to expose the at least one barb extending away from the distal end of the inner cylinder, the inner cylinder is positioned toward the diseased heart valve so as to spear the at least one barb therethrough, and the outer tube is rotated around the inner cylinder so as to rotate the three blades to cut the diseased valve.

In another form of the present invention, there is provided a method for resecting a diseased heart valve, the method comprising:

providing apparatus for resecting a diseased heart valve, the apparatus comprising:

an inner cylinder having an outer tube rotatably disposed thereto, the inner cylinder and outer tube having a distal end and a proximal end, and the inner cylinder defining a longitudinal axis from the distal end to the proximal end;

at least one barb extending away from the distal end of the inner cylinder; and

three blades pivotally attached to the distal end of the outer tube, the three blades being

selectively configurable in a first position and a second position, the first position configured with the blades closed toward one another so as to cover the at least one barb and provide a narrow cross-section thereto in a perpendicular direction to the longitudinal axis, and a second position configured with the blades opened away from one another so as to expose the at least one barb and provide a cutting diameter having a greater cross-section therethrough than the narrow cross-section in the perpendicular direction to the longitudinal axis;

wherein the three blades closed toward one another through a body to a location are positioned adjacent to a diseased heart valve, the three blades are opened away from one another so as to expose the at least one barb extending away from the distal end of the inner cylinder, the inner cylinder is positioned toward the diseased heart valve so as to spear the at least one barb therethrough, and the outer tube is rotated around the inner cylinder so as to rotate the three blades to cut the diseased valve;

positioning the three blades toward the diseased heart valve;

opening the three blades away from one another so as to expose the at least one barb;

spearing the at least one barb through the diseased heart valve; and

rotating the three blades so as to cut the diseased valve.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a chamber having a proximal end and a distal end, and a sidewall extending between the proximal end and the distal end;

a retractable barb selectively positionable between a first position and a second position, the retractable bar being configured within the distal end of chamber in the first position, and the retractable bar being configured to extend beyond the distal end of the chamber in the second position; and

a set of blades surrounding the distal end of the chamber;

wherein the retractable barb extends from the chamber, pierces a portion of the diseased heart valve, and retracts into the chamber; and

wherein the set of blades cuts through the portion of the diseased heart valve pierced by the retractable barb as the retractable barb retracts into the chamber.

In another form of the present invention, there is provided a method for resecting a diseased heart valve, the method comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a chamber having a proximal end and a distal end, and a sidewall extending between the proximal end and the distal end;

a retractable barb selectively positionable between a first position and a second position, the retractable bar being configured within the distal end of chamber in the first position, and the retractable

bar being configured to extend beyond the distal end of the chamber in the second position; and

a set of blades surrounding the distal end of the chamber;

wherein the retractable barb extends from the chamber, pierces a portion of the diseased heart valve, and retracts into the chamber; and

wherein the set of blades cuts through the portion of the diseased heart valve pierced by the retractable barb as the retractable barb retracts into the chamber;

positioning the distal end of the chamber adjacent to the diseased heart valve;

extending the retractable barb from the chamber;

piercing the portion of the diseased heart valve with the retractable barb;

retracting the retractable barb into the chamber; and

cutting through the portion of the diseased heart valve pierced by the retractable barb with the set of blades.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a body portion having a proximal end and a distal end, the body portion defining a longitudinal axis from the proximal end to the distal end, and the body portion defining an opening at the distal end thereof;

a grasping tool being selectively positionable within the body portion along the longitudinal axis from a first position to a second position, the grasping tool being configured within the body portion in the first position, the grasping tool extending through the opening at the distal end of the body portion in the second position, and the grasping tool being configured to selectively close together a first portion and a second portion so as to selectively grip the diseased heart valve therebetween; and

a cutting element disposed within the body portion at a given distance from the opening, the cutting element configured to close together to cut the diseased heart valve therebetween at the given

distance from the opening after the grasping tool is withdrawn to a given location between the cutting element and the proximal end of the body portion;

wherein a portion of the diseased heart valve portion cut away from an intact portion of the diseased heart valve is contained within the body portion.

In another form of the present invention, there is provided a method of resecting a diseased heart valve, the method comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a body portion having a proximal end and a distal end, the body portion defining a longitudinal axis from the proximal end to the distal end thereof, and the body portion defining an opening at the distal end;

a grasping tool being selectively positionable within the body portion along the longitudinal axis from a first position to a second position, the grasping tool being configured within

the body portion in the first position, the grasping tool extending through the opening at the distal end of the body portion, and the grasping tool being configured to selectively close together a first portion and a second portion so as to selectively grip the diseased heart valve therebetween; and

a cutting element disposed within the body portion at a given distance from the opening, the cutting element configured to close together to cut the diseased heart valve therebetween at the given distance from the opening after the grasping tool is withdrawn to a given location between the cutting element and the proximal end of the body portion;

wherein a portion of the diseased heart valve portion cut away from an intact portion of the diseased heart valve is contained within the body portion;

positioning the distal end of the body portion adjacent to the diseased heart valve;

extending the grasping tool through the opening in the body portion to the diseased heart valve portion;

closing the first portion and the second portion of the grasping tool toward one another so as to secure a portion of the diseased heart valve therebetween;

retracting the grasping tool into the body element past the cutting element to the given location between the cutting element and the proximal end of the body portion so as to allow the cutting element to close and cut the portion of the diseased heart valve at the given distance from the opening.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a body portion having a first end and a second end in opposition to one another, a lateral wall extending from the first end to the second end, the lateral wall defining an inner surface and an outer surface in opposition to one another, the inner

surface and the outer surface defining arcuate surfaces, respectively, and the body portion defining a longitudinal axis from the first end to the second end;

a first handle and a second handle attached to the body portion to extend from the first end thereof and the second end thereof, respectively;

a cutting blade selectively rotatable about the longitudinal axis and disposed adjacent to the inner surface of the body portion;

a set of retaining arms positionably mounted between the second handle and the second end of the body portion, the set of retaining arms being selectively positionable from a contracted state to an expanded state, the contracted state forming a first diameter having a first width in a direction perpendicular to the longitudinal axis of the body portion, the expanded state forming a second diameter having a second width in a direction perpendicular to the longitudinal axis of the body portion, the second width being larger than a first width of the first

diameter in the direction perpendicular to the longitudinal axis of the body portion;

a pass-off tool having a proximal end and a distal end, a first attachment device at the distal end thereof, the first attachment device configured to selectively engage the first handle attached to the body portion so as to allow placement of the second handle of the body portion adjacent to the diseased heart valve; and

a controller tool having a proximal end and a distal end, a second attachment device at the distal end thereof, the second attachment device configured to selectively engage the second handle attached to the body portion so as to allow positioning of the second end of the body portion adjacent to the diseased heart valve, a cutting blade actuator configured to cause the cutting blade to selectively rotate relative to the longitudinal axis of the body portion, and a retaining arm actuator configured to selectively position the set of retaining arms from the contracted state to the expanded state.

In another form of the present invention, there is provided a method for resecting a diseased heart valve, the method comprising:

providing apparatus for resecting a diseased heart valve, the apparatus comprising:

a body portion having a first end and a second end in opposition to one another, a lateral wall extending from the first end to the second end, the lateral wall defining an inner surface and an outer surface in opposition to one another, the inner surface and the outer surface defining arcuate surfaces, respectively, and the body portion defining a longitudinal axis from the first end to the second end thereof;

a first handle and a second handle attached to the body portion to extend from the first end thereof and the second end, respectively;

a cutting blade selectively rotatable about the longitudinal axis and disposed adjacent to the inner surface of the body portion;

a set of retaining arms positionably mounted between the second handle and the second end of the body portion, the set of retaining arms being selectively positionable from a contracted state to an expanded state, the contracted state forming a first diameter having a first width in a direction perpendicular to the longitudinal axis of the body portion, the expanded state forming a second diameter having a second width in a direction perpendicular to the longitudinal axis of the body portion, the second width being larger than a first width of the first diameter in the direction perpendicular to the longitudinal axis of the body portion;

a pass-off tool having a proximal end and a distal end, a first attachment device at the distal end thereof, the first attachment device configured to selectively engage the first handle attached to the body portion so as to allow placement of the second handle of the body portion adjacent to the diseased heart valve; and

a controller tool having a proximal end and a distal end, a second attachment device at the distal end thereof, the second attachment device configured to selectively engage the second handle attached to the body portion so as to allow positioning of the second end of the body portion adjacent to the diseased heart valve, a cutting blade actuator configured to cause the cutting blade to selectively rotate relative to the longitudinal axis of the body portion, and a retaining arm actuator configured to selectively position the set of retaining arms from the contracted state to the expanded state;

engaging the first handle attached to the body portion with the pass-off tool;

positioning the second handle of the body portion adjacent to the diseased heart valve;

engaging the second handle attached to the body portion with the controller tool;

disengaging the pass-off tool and the first handle from one another;

positioning the second end of the body portion adjacent to the diseased heart valve;

expanding the set of retaining arms with the retaining arm actuator so as to hold the cut portion of the diseased heart valve within the body portion;

rotating the cutting blade relative to the longitudinal axis of the body portion with the cutting blade actuator;

positioning the body portion toward the diseased heart valve with the controller tool so as to cut the diseased heart valve.

In another form of the present invention, there is provided an apparatus for resecting a diseased heart valve, the apparatus comprising:

a cylindrical body portion having a first end and a second end;

a first handle and a second handle attached to the body portion to extend from the first end thereof and the second end thereof, respectively;

a cylindrical cutting blade selectively rotatable about the longitudinal axis and disposed within the body portion;

a set of retaining arms positionably mounted therebetween the second handle and the second end of the body portion, the set of retaining arms being selectively positionable from a contracted state to an expanded state, the contracted state forming a first diameter having a first width in a direction perpendicular to the longitudinal axis of the body portion, the expanded state forming a second diameter having a second width in a direction perpendicular to the longitudinal axis of the body portion, the second width being larger than a first width of the first diameter in the direction perpendicular to the longitudinal axis of the body portion.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description

of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like elements and further wherein:

Fig. 1 is a schematic side view showing the introduction of a valve prosthesis and prosthesis holding apparatus into the left atrium of the heart, through an atriotomy, using a first manipulation instrument;

Fig. 2 is a schematic side view showing passage of the apparatus of Fig. 1 from the left atrium, through the mitral valve, and into the left ventricle;

Fig. 3 is a schematic side view showing the introduction of a second manipulation instrument into the left ventricle through an arteriotomy into the arterial system;

Fig. 4 is a schematic side view showing the second manipulation instrument being attached to the prosthesis holding apparatus while the first manipulation instrument remains secured to the prosthesis holding apparatus;

Fig. 5 is a schematic side view similar to that of Fig. 4, except showing the first manipulation instrument being removed from the surgical site while the second manipulation instrument remains secured to the prosthesis holding apparatus;

Fig. 6 is a schematic side view showing the second manipulation instrument positioning the prosthetic valve within the aorta prior to fixation;

Fig. 7 is a schematic side view showing the prosthetic valve secured to the tissues of the aorta following removal of the second manipulation instrument and prosthesis holding apparatus;

Figs. 8, 9 and 10 are enlarged schematic views showing a preferred construction for the valve holding apparatus, and for the attachment to, and detachment from, the prosthetic valve;

Fig. 11 is a schematic view showing a guide for guiding the second manipulation instrument relative to the first manipulation instrument such that the second manipulation instrument will be aimed directly at the

second manipulation mount when the first manipulation mount is secured to the first manipulation instrument;

Fig. 12 is a perspective view of a preferred embodiment of the present invention for a punch configured for a left ventrical approach to a diseased valve;

Figs. 13-17 are schematic views of preferred embodiments of the present invention for a punch configured for an aortic approach to a diseased valve;

Figs. 18-22 are schematic views of preferred embodiments of the present invention for resection of a heart valve using a power shaver in combination with a power shaver guide;

Figs. 23-32 are schematic views of an expandable resector views of an expandable resector with three arms, in which one of the arms carries a cutting device;

Figs. 33-37 are schematic views of a spiked resector for holding portions of the valve prior to closing the cutting portions together;

Figs. 38-49 are schematic views of a preferred embodiment of the present invention including an expandable blade resector delivered through a catheter;

Figs. 50-57 are schematic views of a preferred embodiment of the present invention including an expandable cylinder resector delivered through a catheter;

Figs. 58-60 are schematic views of a preferred embodiment of the present invention including a power auger cutter for cutting and removing portions of a heart valve;

Figs. 61-63 are schematic views of a preferred embodiment of the present invention including an offset cutter;

Figs. 64-70 are schematic views of a preferred embodiment of the present invention including a trisector having three cutting blades;

Figs. 71-76 are schematic views of a preferred embodiment of the invention including a valve entrapment cutter;

Figs. 77-79 are schematic views of a preferred embodiment of the invention including a gripper cutter having a pair of graspers and a cutting element;

Figs. 80-90 are schematic views of a preferred embodiment of the present invention including a valve cutter and resector for use with a left ventrical approach;

Fig. 91 is a schematic view of a resection tool having several different types of protective guides; and

Fig. 92-101 are schematic views of a preferred embodiment of the present invention including a valve cutter and resector for use with a left ventrical approach, the valve cutter and resector having an umbrella covered by filter material.

Detailed Description Of The Preferred Embodiments

The present invention can be used to implant a variety of prostheses into the arterial system or left side of the heart. The prosthesis used in the preferred embodiment is an aortic valve prosthesis.

Alternatively, the prosthesis may comprise, but is not limited to, a cylindrical arterial stent, an arterial prosthesis or graft, a ventricular assist device, a device for the treatment of heart failure such as an intraventricular counterpulsation balloon, chordae tendinae prostheses, arterial filters suitable for acute or chronic filtration of emboli from the blood stream, arterial occlusion devices and the like.

For clarity of illustration, the present invention will hereinafter be discussed in the context of implanting an aortic valve prosthesis.

It should also be appreciated that the present invention may be practiced either "on-pump" or "off-pump". In other words, the present invention may be performed either with or without the support of cardiopulmonary bypass. The present invention also may be performed either with or without cardiac arrest.

Looking now at Fig. 1, there is shown an exemplary embodiment of the present invention. A prothesis holding apparatus 100 is secured to a

prosthetic valve 200 so as to form a temporary prosthetic assembly 300. A first manipulation instrument 400 is secured to a first manipulation mount 105 formed on prosthesis holding apparatus 100, whereby temporary prosthetic assembly 300 may be moved about by first manipulation instrument 400. Temporary prosthetic assembly 300 has been positioned in left atrium 5 by passing first manipulation instrument 400 through atriotomy 10. Alternatively, the temporary prosthetic assembly 300 could be passed into the left atrium 5, using first manipulation instrument 400, through any of the pulmonary veins 15 (not shown). And in another form of the invention, temporary prosthesis assembly 300 could be passed into the left atrium by first passing the assembly into the right atrium via an atriotomy, and then into the left atrium through an incision made in the interatrial septum.

Prosthetic valve 200 is preferably a conventional mechanical aortic valve of the sort well known in the art, although other forms of valve prostheses may also be used.

In one preferred form of the invention, first manipulation instrument 400 functions by virtue of the relative motion of an outer cannula 405 relative to an inner grasper 410. More particularly, inner grasper 410 has an elastically deformable distal gripper 415 which is open when the gripper is outside of outer cannula 405. However, when deformable gripper 415 is pulled at least partially into or against outer cannula 405, gripper 415 is elastically deformed into a closed position, whereby it may grip an object, e.g., first manipulation mount 105 formed on prosthesis holding apparatus 100. First manipulation instrument 400 is shown in Fig. 1 in its closed position, wherein deformable gripper 415 is closed about first manipulation mount 105, such that prosthesis holding apparatus 100, and hence the entire temporary prosthetic assembly 300, is held secured to the distal end of first manipulation instrument 400.

The specific embodiment of first manipulation instrument 400 shown in Fig. 1 is presented as an illustrative example only, and is not intended to

limit the scope of the present invention. Many other arrangements may be used for releasably gripping first manipulation mount 105 formed on prosthesis holding apparatus 100. Furthermore, first manipulation mount 105 may itself have many potential shapes and properties to enable releasable attachment to first manipulation instrument 400. Other possible configurations for releasably securing first manipulation mount 105 to first manipulation instrument 400 include, but are not limited to, opposing magnet poles in the mount and instrument, adhesives, a press fit between mount and instrument, threaded couplings, suture loops, a balloon or balloons expanded within a mating cavity, collapsible barbs, etc. For the purposes of the present invention, the important point is that some arrangement be provided for releasably securing the prosthesis holding apparatus (and hence the prosthetic valve) to a manipulation instrument.

Still looking now at Fig. 1, first manipulation instrument 400 is shown as having a long axis that

extends outside of the heart, with first manipulation instrument 400 being straight along that axis. However, it should also be appreciated that first manipulation instrument 400 may, alternatively, be formed with a curve at one or more location along this length. Furthermore, first manipulation instrument 400 may be constructed so as to allow articulation at the distal end, the proximal end, or both, or at any point therebetween. In addition, first manipulation instrument 400 may be formed either entirely rigid or substantially flexible, along all or part of its length.

First manipulation instrument 400 is also shown as having a relatively small dimension perpendicular to its long axis. This configuration allows atriotomy 10 to be reduced in size after the passage of temporary prosthetic assembly 300 into left atrium 5. This perpendicular dimension may be constant or varied along the long axis of first manipulation instrument 400.

The specific embodiment of the prosthesis holding apparatus 100 shown in Fig. 1 is presented as an illustrative example only, and is not intended to limit the scope of the present invention. Many other arrangements may be used for releasably gripping prosthetic valve 200 and for providing first manipulation mount 105, as well as providing a second manipulation mount 110 that will be discussed below. In Fig. 1, first manipulation mount 105 and second manipulation mount 110 are shown as spherical additions to struts 115 extending away from prosthetic valve 200. These spheres are intended to fit, respectively, within the deformable gripper 415 of first installation instrument 400 and the deformable gripper 515 of a second installation instrument 500 (discussed below). First manipulation mount 105 and/or second manipulation mount 110 could, alternatively, be indentations within a portion of male or female threaded extensions from, magnetized surfaces of, slots or holes in or through, prosthesis holding apparatus 100, etc. Furthermore, first

manipulation mount 105 and/or second manipulation mount 110 could be portions of the struts 115 extending away from prosthetic valve 200, where those portions may be either reduced or enlarged in dimension relative to neighboring portions of the struts. Many other constructions may also be used to form first manipulation mount 105 and second manipulation mount 110. For the purposes of the present invention, the important point is that some arrangement be provided for releasably securing the prosthesis holding apparatus (and hence the prosthetic valve) to manipulation instruments.

Still looking now at Fig. 1, it will be appreciated that the native aortic valve has been removed. Removal of the native aortic valve is not a necessary element of the present invention, but may be incorporated into the preferred method. Removal of the native aortic valve may be accomplished either before or after passage of the temporary prosthetic assembly 300 into left atrium 5.

When the methods and devices of the present invention are employed during an off-pump valve replacement procedure, it may be beneficial to provide temporary valves and/or filters in the arterial system, downstream of the site of the native aortic valve. Thus, for example, in Fig. 1 there is shown a temporary valve 600 (not shown in the remaining figures) which may be used to support cardiac function during and following removal of the diseased cardiac valve. Temporary valve 600 is shown positioned in aorta 20. Alternatively, temporary valve 600 may be positioned in the aortic arch or the descending aorta. In addition, temporary valve 600 may incorporate a filter therein to mitigate the risks of embolic complications. Alternatively, a separate filter may be employed within the aorta and/or the branch arteries extending therefrom.

Fig. 2 shows first manipulation instrument 400 being used to manipulate temporary prosthetic assembly 300 (and hence prosthetic valve 200) into left ventricle 25 through mitral valve 30. After temporary

prosthetic assembly 300 has passed into left ventrical 25, the first manipulation instrument 400 will continue to traverse mitral valve 30; however, the reduced perpendicular cross-section of first manipulation instrument 400 will cause only minimal disruption of the function of mitral valve 30.

Fig. 3 shows the insertion of a second manipulation instrument 500 through the arterial system and into left ventricle 25. Second manipulation instrument 500 is shown being inserted through an incision 35 on aorta 20. Alternatively, second manipulation instrument 500 could be inserted into a central or peripheral artery and than advanced into left ventricle 25. Aortic incision 35 is small relative to the atriotomy 10 formed in left atrium 5.

Bleeding through incision 35 may be readily controlled through a variety of means. These include, but are not limited to, employing a valved or un-valved arterial cannula, a purse-string suture placed around incision 35 and then pulled tight about second manipulation instrument 500, a side-arm graft

sewn to aorta 20 that may be constricted about a region of second manipulation instrument 500, the use of a tight fit between a portion of second manipulation instrument 500 and aortic incision 35, etc.

Second manipulation instrument 500 is shown in Fig. 3 as being of the same form and function of first manipulation instrument 400. Again, outer cannula 505 fits around inner grasper 510, and the relative motion between grasper 510 and cannula 505 can be used to deform gripper 515 between open and closed positions. Alternatively, second manipulation instrument 500 may have any of the variety of other forms and functions described above with respect to first manipulation instrument 400. Furthermore, second manipulation instrument 500 is preferably of a smaller dimension perpendicular to its long axis than first manipulation instrument 400 so as to reduce the risks posed by arteriotomy 35.

Fig. 4 shows second manipulation instrument 500 being secured to the second manipulation mount 110

formed on prosthesis holding apparatus 100. This is done while first manipulation instrument 400 is secured to first manipulation mount 105 formed on prosthesis holding apparatus 100, in order that temporary prosthetic assembly 300 will be under control at all times during the "hand-off" between first manipulation instrument 400 and second manipulation instrument 500.

It should be appreciated that the orientation of second manipulation mount 110 is preferably such as to enable the long axis of second manipulation instrument 500 to be substantially perpendicular to the flow area of prosthetic valve 200. This arrangement is particularly helpful when guiding prosthetic valve 200 into its final position within aorta 20 as shown hereafter in Figs. 6 and 7.

The use of two separate manipulation instruments, and the method of passing valve prosthesis 200 from one to the other, avoids the complex manipulations of valve prosthesis 200 that would be required to position valve 200 within aorta 20 using only a single

manipulation instrument introduced through the left atrium. In this respect it should be appreciated that such a "single manipulation instrument" technique has been found to be possible, however, and is best facilitated by using a manipulation instrument capable of bending or articulating at or near the site of its attachment to valve holding apparatus 100. In this respect it has been found that it can be particularly advantageous to provide a manipulation instrument capable of bending or articulating within about 4 cm or so of the point of attachment to valve holding apparatus 100. It has also been found that it can be particularly advantageous for such an articulating instrument to be able to deflect its distal tip by an angle of between about 90 to 180 degrees from the long axis of the first manipulation instrument 400 shown in Fig. 4.

The angular offset of first manipulation mount 105 and second manipulation mount 110 is preferably set to facilitate passage of temporary prosthetic assembly 300 from left atrium 5 to aorta 20 using two

substantially straight manipulation instruments, e.g., first manipulation instrument 400 and second manipulation instrument 500. This angle is preferably approximately 45 degrees. However, this angle may also be varied so as to optimize passage of different valve designs or other prostheses using curved, straight or articulating manipulation instruments from various access sites into the left atrium and arterial system. This angle may be fixed or variable on a given prosthesis holding apparatus 100.

Once second manipulation instrument 500 is safely secured to second manipulation mount 110, first manipulation instrument 400 may be released from first manipulation mount 105 and removed from left ventricle 5, as shown in Fig. 5. Alternatively, first manipulation instrument 400 may remain secured to prosthesis holding apparatus 100 or prosthetic valve 200 by a flexible tether so as to facilitate re-attachment of first manipulation instrument 400 to valve holding apparatus 100 if necessary.

Fig. 6 shows temporary prosthesis assembly 300 being positioned by second manipulation instrument 500 at a preferred fixation site. This fixation site is preferably upstream of or proximal to the coronary arteries, although this position is not a restrictive requirement of the present invention.

Fig. 7 shows valve prosthesis 200 secured to the walls of aorta 30 and removal of second manipulation instrument 500 and prosthesis holding apparatus 100. In this respect it should be appreciated that prosthesis holding apparatus 100 is preferably wholly or partially flexible, or otherwise collapsible, so as to allow the prosthesis holding apparatus 100 to be collapsed radially and then withdrawn through arteriotomy 35 after prosthesis holding apparatus 100 has been released from prosthetic valve 200. Alternatively, prosthesis holding apparatus 100 may be removed from the vascular system, either partially or entirely, through atriotomy 10 by first manipulation instrument 400, by a tether leading therefrom, or a separate instrument. Of course, in the situation

where prosthesis holding apparatus 100 is to be removed via atriotomy 10, the prosthesis holding apparatus 100 should be appropriately mounted to prosthetic valve 200, i.e., prosthesis holding apparatus 100 should be positioned on the atriotomy side of the valve.

In Fig. 7, valve prosthesis 200 is shown secured to aorta 30 using barbs or staples 700. Barbs or staples 700 may be a component of, and/or deployed from, prosthesis holding apparatus 100, and/or valve prosthesis 200, and/or a separate fixation device. Alternatively, barbs or staples 700 may be deployed by a separate instrument inserted through the outer surface of aorta 30, from a remote site in the arterial system, through atriotomy 10 or through some other incision into a cardiac chamber or great vessel.

Looking next at Figs. 8-10, there is shown one preferred configuration for prosthesis holding apparatus 100. More particularly, prosthesis holding apparatus 100 comprises a base 120 having a longitudinal opening 123 (Fig. 9) therein for slidably

receiving a rod 125 therethrough. Base 120 also comprises a plurality of side slots 130. Each side slot 130 has a strut 115 pivotally connected thereto. Slots 130 are constructed so that each strut 115 can pivot freely between (i) the position shown in Figs. 8 and 9, and (ii) the position shown in Fig. 10. A body 135 is mounted on rod 125. A plurality of wire fingers 140 are secured to body 135. Wire fingers 140 extend through holes 145 formed in base 120 and extend around the cuff 205 of prosthetic valve 200. Second manipulation mount 110 is secured to the proximal end of rod 125. First manipulation mount 105 is secured to one of the struts 115. Alternatively, as noted above, first manipulation mount 105 may be formed by a strut 115 itself, provided that first manipulation instrument 400 is appropriately adapted to engage the strut 15 directly.

In use, prosthesis holding apparatus 100 is fit about valve prosthesis 200 so that wire fingers 140 hold valve cuff 205 to struts 115. Prosthesis holding apparatus 100 is then engaged by first manipulation

instrument 400, using first manipulation mount 105, and moved into and through right atrium 5, through mitral valve 30 and into left ventricle 25. Then second manipulation tool 500, comprising outer cannula 505 and inner grasper 510 having the deformable gripper 515, engages second manipulation mount 110. The distal tip 520 of outer cannula 505 is placed against edge 150 of base 120 and gripper 515 is drawn proximally within outer cannula 505 until deformable gripper 515 engages shoulder 525, whereupon prosthesis holding apparatus 100 (and hence prosthetic valve 200) will be mounted to second manipulation tool 500. Second manipulation tool 500 is then used to maneuver temporary prosthetic assembly 300 into position, whereupon the valve's cuff 205 is secured to the side wall of the aorta, e.g., with barbs, staples, suture, etc. Then prosthesis holding apparatus 100 is detached from prosthetic valve 200 by pulling inner grasper 510 proximally relative to outer cannula 505 so that wire fingers 140 are pulled free from valve cuff 205 (Fig. 9), whereby to free prosthesis holding

apparatus 100 from the prosthetic valve 200. Then second manipulation instrument 500 is withdrawn out aorta 20 and arteriotomy 35, with struts 115 folding inwardly (Fig, 10) so as to pass through the arteriotomy. Struts 115 can be adapted to fold inwardly through engagement with the walls of the arteriotomy 35 or, alternatively, additional means (such as springs, cams, etc.) can be provided to fold struts 115 inwardly.

In practice, it has been found that it can sometimes be difficult to locate second manipulation mount 110 with second manipulation instrument 500 so as to "hand off" temporary prosthesis assembly 300 from first manipulation instrument 400 to second manipulation instrument 500. This can be particularly true where the procedure is to be conducted "off-pump", i.e., without stopping the heart. To this end, and looking now at Fig. 11, there is shown a guide 800 for guiding second manipulation instrument 500 relative to first manipulation instrument 400 such that second manipulation instrument 500 will be aimed

directly at second manipulation mount 110 when first manipulation mount 105 is secured to first manipulation instrument 400. More particularly, guide 800 comprises a first passageway 805 for slidably receiving first manipulation instrument 400, and a second passageway 810 for slidably receiving second manipulation instrument 500. Passageways 805 and 810 are oriented so that second manipulation instrument 500 will be aimed directly at second manipulation mount 110 when temporary prosthesis assembly 300 is held by first manipulation instrument 400 engaging first manipulation mount 105.

In accordance with the present invention, it is also possible to enter the left atrium other than through an exterior wall of the left atrium. Thus, for example, it is possible to introduce the prosthetic valve through an opening in an exterior wall of the right atrium, pass the prosthetic valve through an incision in the interatrial septum and across to the left atrium, and then advance the

prosthetic valve to its implantation site via the mitral valve and the left ventricle.

As noted above, the manipulation instrument(s) do not need to take the form of the installation instrument 400 or 500. It is also possible to deliver the prosthetic valve to its implant site using a guidewire and a pusher tool riding on the guidewire.

Thus, for example, in an alternative preferred embodiment, a wire, a catheter, a tube or any other filament can be placed from the left atrium, through the ventricle and into the arterial system, over (or through) which a prosthesis or device can be advanced (pushed or pulled). As an example, a catheter with a balloon can be placed through an incision in the left atrial wall. The balloon can be inflated and this catheter can then be "floated" along the flow of blood across the mitral valve, into the left ventricle, and out into the arterial system. At that point the catheter can be grasped by an instrument placed through a small incision in the aorta or passed into the aorta by means of a remote vessel such as the

femoral artery. At this point, the prosthesis or device can be mounted onto the catheter and either be pushed (or pulled) over the catheter into position. This procedure can be similarly performed by the use of a wire or other filament structure. Also, a tube could be employed, with the prosthesis or device being advanced within the tube.

Looking now at Figs. 12-91, several preferred embodiments of the present invention are shown for removing a diseased valve without causing stroke or other ischemic events that might result from the liberation of particulate material. Valve resection may be necessary prior to valve replacement of a diseased valve, such as a stenotic valve, which will not open, or an insufficient valve, which will not close. In addition, the diseased valve may also be calcified or have a torn leaflet. In some of the preferred embodiments of the present invention, a crushing force is delivered to the diseased valve so as to displace the diseased valve prior to implantation of a replacement valve. However,

adequate displacement of the diseased valve prior to implantation of a replacement valve may not be possible due to calcification or displacement alone may not allow the desired placement of the replacement valve. Several preferred embodiments of the present invention are configured to cut away and remove the diseased valve, rather than only crush it, so as to allow implantation of the replacement valve at a desired location.

Referring now to Fig. 12, a valve punch 900 is shown having a first frame member 905 and a second frame member 910 positioned relative to one another by an adjustable connector 915. In a preferred embodiment of the present invention, first frame member 905 holds a blade 920 configured to form a closed perimeter and with its cutting surface facing toward second frame member 910. Second frame member 910 is configured with a corresponding cutting surface 925 facing toward the blade 920.

In use, punch 900 is positioned at a diseased valve (not shown) with adjustable connector 915

operated to space first frame member 905 and second frame member 910 apart from one another so as to receive at least a portion of the diseased valve (not shown) therebetween. Next, adjustable connector 915 is operated so as to close first frame member 905 and second frame member 910 toward one another. This action causes blade 920 to move past cutting surface 925 so as to sever the portion of the diseased valve (not shown) therebetween. Punch 900 may be removed with the resected valve contained between first frame member 905 and second frame member 910. Punch 900 may be configured for either an approach to the valve through the aorta, referred to as an aortic approach, or an approach to the valve through the left ventricle of the heart, referred to as a left ventrical approach.

In a preferred embodiment of the present invention, and still referring to Fig. 12, punch 900 is configured to allow blood flow through first frame member 905 and second member 910. Screen portions 930 may be provided on first frame member 905 and second

frame member 910 so as to contain small pieces of the resected valve, which may otherwise be carried away.

Adjustable connector 915 of punch 900 is preferably configured with a handle 935 for opening and closing first frame portion 905 and second frame portion 910 relative to one another. A spring 940 is also provided to bias first frame portion 905 and second frame portion 910 closed relative to one another. This configuration of punch 900 may be used in connection with the left ventrical approach with handle 935 being operable with a two tube controller (not shown). Alternatively, the shaft of adjustable connector 915 may be threadably connected to either first frame member 905 or second frame member 910 so as to allow adjustable connector 915 to open or close punch 900 with a twisting motion.

Looking now at Figs. 13-17, an aortic approach punch 945 is shown for resecting diseased valve (not shown) using an aortic approach. Aortic approach punch 945 includes a first frame member 950 and a second frame member 955, with the two frame members

being selectively movable by an actuator 960 so as to engage one another. First frame member 950 and second frame member 955 contain cutting edges 965, 970, respectively. Cutting edges 965, 970 engage with one another as operated by actuator 960 so as to sever and contain a portion of an aortic valve 975 positioned therebetween.

In a preferred embodiment of the present invention, first frame member 950 and second frame member 955 each contain a mesh filter 980. Each mesh filter 980 allows blood flow through punch 945 and prevents portions of the resected valve larger than openings in mesh filter 980 from passing through punch 945.

Looking now at Fig. 16, second frame member 955 is shown with a seat 985 for holding a portion of the resected valve against a corresponding structure of first frame member 950. Seat 985 is configured with voids 990 so as to permit blood flow through punch 945 while simultaneously holding the resected portion.

Looking now at Fig. 17, the aortic approach punch 945 is shown with first frame member 950 and second frame member 955 each having cutting teeth 995 in rotatable engagement with one another. Actuator 960 is configured to rotate and engage first frame member 950 and second frame member 955 relative to one another so as to cut portions of an aortic valve therebetween using cutting teeth 995.

Referring now to Fig. 18-22, a power shaver guide 1000 is shown for resecting a heart valve with a power shaver 1005, such as a commercially available arthroscopic device. Power shaver guide 1000 includes an opening 1010 to receive power shaver 1005 therethrough. Power shaver guide 1000 is sized to fit within the aorta. Preferably, power shaver guide 1000 is sized large enough to prevent power shaver 1005 from unintentionally cutting through a wall of the aorta but small enough to fit inside of the diseased valve. In addition, the diseased valve may be crushed prior to introduction of power shaver guide 1000 and power shaver 1005.

Looking now at Figs. 18 and 19, a cutting window 1015 is provided in power shaver guide 1000 to allow cutting therethrough and to shield power shaver 1005 from cutting through the wall of the aorta.

Looking now at Figs. 20 and 21, power shaver guide 1000 is shown with opening 1010 configured to hold power shaver 1005 positioned therethrough without requiring cutting window 1015 (see Figs. 18 and 19).

Looking now at Fig. 22, in another preferred embodiment of the invention, power shaver guide 1000 is collapsible. Collapsible power shaver guide 1000 preferably comprises an inflatable balloon 1020. Inflatable balloon 1020 is shown in a collapsed state for insertion into the aorta and in an inflated state for resection of the diseased valve.

Looking now at Figs. 23-32, in another preferred embodiment of the present invention, there is shown an expandable resector 1025 having three expandable arms 1030, in which one expandable arm 1030 carries a cutting device 1035. Cutting device 1035 includes a wire 1040, which is either rotary driven or

reciprocically driven, so as to cut portions of a diseased valve. Wire 1040 is positioned within expandable arm 1030 to create a cutting window 1045. Cutting window 1045 may be formed either by recessing wire 1040 into expandable arm 1030 or by building up the portions of expandable arm 1030 surrounding cutting window 1045.

Wire 1040 may include a rough, abrasive surface for rotary driven or reciprocically driven cutting. Alternatively, wire 1040 may include an electrocautery element for cutting. A power shaver may also be used in place of wire 1040. The rough or abrasive embodiment of wire 1040 may include recesses formed in the wire 1040 or an abrasive metal dust coating added to it.

Looking now at Figs. 33-37, in another preferred embodiment of the present invention, there is shown a spiked resector 1050. Spiked resector 1050 includes at least two spikes 1055 to hold valve leaflets in place as frame members 1065, 1070 are advanced toward one another. Spiked resector 1050 also includes a

spike receiving portion 1060 to allow frame members 1065, 1070 to closely approach one another in order that a cutting mechanism 1075 (Fig. 37) cuts through the valve leaflets. In addition, one of the frame members 1065, 1070 may be mounted to a screw-driven assembly 1080 so as to axially rotate the mounted frame member to aid in cutting.

Referring now to Figs. 38-49, in another preferred embodiment of the present invention, there is shown an expandable blade resector 1085 for resection of a heart valve using a catheter 1090. Expandable blade resector 1085 includes a set of blades 1095 and a hinged portion 1100. Blades 1095 and hinged portion 1100 are selectively positionable through catheter 1090. In a preferred embodiment of the present invention, expandable blade resector 1085 includes a filter mesh portion 1105 (Fig. 44) at a distal end thereof covering hinge 1095. Filter mesh portion 1105 acts to capture portions of the resected valve. Blades 1095 may also be serrated to aid in cutting through a valve.

Looking now at Figs. 50-57, in another preferred embodiment of the present invention, there is shown an expandable cylinder resector 1110 for resection of a heart valve using a catheter 1115. Expandable cylinder resector 1110 includes an inner rod 1120 attached to catheter 1115, an outer shell 1125 attached to inner rod 1120 at a first portion 1130 and in surrounding relation to inner rod 1120, and a spring 1135 being attached to outer shell 1125 at a second portion 1138 and contained by outer shell 1125. Expandable cylinder resector 1110 is operated by placing the outer shell 1125 within a portion of a heart valve and then turning inner rod 1120 to allow spring 1135 to expand the diameter of outer shell 1125 relative to inner rod 1120. In this configuration, expandable cylinder resector 1110 may be used to crush portions of a valve and/or as a centering guide in combination with another resecting tool shown mounted at 1140 (Fig. 55).

Looking now at Figs. 53 and 54, inner rod 1120 is preferably adjustable to selectively open and close

together two portions 1145, 1150 of outer shell 1125. These portions 1145, 1150 may be placed in an open position adjacent to an aortic valve and then actuated by inner rod 1120 to a closed position so as to cut through the aortic valve.

Referring now to Figs. 58-60, in another preferred embodiment of the present invention, there is shown a power auger cutter 1155 for cutting and removing portions of a heart valve. Power auger cutter 1155 includes a tubular body 1160 containing an auger blade 1165. An opening 1170 is formed in tubular body 1160 to allow portions of a heart valve into the interior of power auger cutter 1155. Power auger cutter 1155 is configured to cut portions of the heart valve extending into opening 1170 by carrying the portions with auger blade 1165 deeper into tubular body 1160 until auger blade 1165 contacts tubular body 1160 at a junction 1180. After the severed portions of the heart valve pass junction 1180, auger blade 1165 continues to carry these portions through tubular body 1160 and out of the aorta.

Looking now at Figs. 58 and 59, power auger cutter 1155 is provided with a set of guides 1185. Guides 1185 are positioned around at least a portion of opening 1170, which acts to shield against cutting the wall of the aorta. Preferably, the width of power auger cutter 1155 is about 0.20% of the aorta.

Looking at Fig. 60, power auger cutter 1155, configured without a set of guides, is preferably used with a delivery system. The delivery system either provides a shield against cutting the wall of the aorta or positions power auger cutter 1155. One such system is the expandable resector with three arms.

Referring now to Figs. 61-63, in a preferred embodiment of the present invention, there is shown an offset cutter 1190. Offset cutter has an inner rod 1195, an outer shell 1200, and a cutting blade 1205 positioned at the end of outer shell 1200. The diameter of outer shell 1200 is controlled by increasing or decreasing its length extending out of inner rod 1195. The large diameter of outer shell 1200 acts as a guide to shield against cutting the

wall of the aorta with cutting blade 1205 as it cuts away portions of a heart valve.

Referring now to Figs. 64-70, in a preferred embodiment of the present invention, there is shown a trisector 1210 having three blades 1215 for resecting a heart valve. In a preferred embodiment of the present invention, barbs 1220 are provided at a center portion of the trisector to spear and hold the leaflets of the heart valve while blades 1215 spin to cut through the heart valve. Blades 1215 may be configured to cut at a forward portion of trisector 1210, in which case trisector 1210 acts as plunging cutter. Alternatively, blades 1215 may be configured to cut at a side portion of the trisector 1210, in which trisector 1210 acts as a side cutter. For very hard calcification of a heart valve, it is preferred that trisector 1210 be configured as a plunging cutter to cut in a forward direction.

In an alternative preferred embodiment of the present invention, trisector 1210 is provided with a filtering mechanism 1220 (Fig. 68) to contain cut away

portions of the valve for removal from the patient's body.

Referring now to Figs. 71-76, in a preferred embodiment of the present invention, there is shown a valve entrapment cutter 1225. Valve entrapment cutter 1225 includes a chamber 1230 with a retractable barb 1235 and a set of blades 1240 surrounding an end of chamber 1230. Blades 1240 may be configured to rotate around barb 1235 so as to cut through a portion of a valve pierced by barb 1235 as the portion enters chamber 1230. Alternatively, chamber 1230 may be configured to rotate around barb 1235 as the portion enters chamber 1230.

Referring now to Figs. 77-79, in a preferred embodiment of the present invention, there is shown a gripper cutter 1240 for the resecting of a portion of a heart valve. Gripper cutter 1240 includes a pair of graspers 1245 contained in a body 1250 with a cutting element 1255 positioned therebetween. Graspers 124 are extended distally from the distal end of body 1250 so as to contact a portion 1260 of a heart valve.

Graspers 1245 are closed together through actuation of either graspers 1245 or body 1250. Graspers 1245 are then retracted with heart valve portion 1260 into body 1250. Cutting element 1255 closes together after graspers 1245 are retracted to a given point proximal to the end of cutting element 1255. This action causes heart valve portion 1260 to be cut away from the remaining portion of the heart valve and to be contained within body 1250.

Referring now to Figs. 80-90, in a preferred embodiment of the present invention there is shown valve cutter and resector 1265 for use in a left ventrical approach. Valve cutter and resector 1265 includes a first handle 1270 for connection to a pass-off tool 1275 located in the left ventricle of the heart, a second handle 1280 for connection to a controller tool 1285 located in the aorta, a body portion 1290 between first handle 1270 and second handle 1280, a cutting blade 1295 axially rotatable on the inside surface of body portion 1290, and a set of retaining arms 1300 (Fig. 86) selectively expandable

from second handle 1280. Valve cutter and resector 1265 is operable to resect a portion 1305 of an aortic valve 1310 by advancing through the left ventrical of the heart to aortic valve 1310 by means of pass-off tool 1275. Next, controller tool 1285 is advanced through the aorta, passes through the opening of aortic valve 1310 and is received by second handle 1280. First handle 1270 is then disengaged from pass-off tool 1275. Controller tool 1285 draws body portion 1290 distally with cutting blade 1295 spinning to cut through aortic valve 1310. Retaining arms 1300 expand from a folded configuration within second handle 1280 and hold resected portion 1305 within body portion 1290. First handle 1270 is repositioned and re-engaged to pass-off tool 1275 for removal through the left ventrical of the heart, with controller tool 1285 being disengaged from second handle 1280.

Referring now to Fig. 91, in a preferred embodiment of the present invention, there is shown a resection tool 1315 having a protective guide

1320A-1320D to prevent cutting of the aortic wall through an opening 1325. In a preferred embodiment of the present invention, protective guide 1320A is a rigid structure in a surrounding configuration to opening 1325. This embodiment is illustrated by the "double bridge" design. In another preferred embodiment of the present invention, protective guide 1320B-1320D is a flexible structure adjacent to opening 1325. This embodiment is illustrated by the "inchworm", "cantilever", and "window slide" designs, in which a maximum deformation of the flexible structure is shown in phantom.

Looking next at Figs. 92-101, there is shown a modified form of valve cutter and resector 1265. Again, this particular embodiment of debridement tool was designed with left atrial insertion and intra-cardiac hand-off in mind. A basic idea of this embodiment is the use of a thin-walled cylinder or body portion 1290 size-specific for the patient's anatomy. Here the tolerances are fairly small. The patient's left ventricular outflow tract and aortic

valve annulus are carefully measured by transesophageal echo. An appropriately sized debridement tool 1265 (with an appropriately sized thin-wall cylinder 1290) is then selected. Within the thin-walled cylinder 1290 is a cylindrical razor or cutting blade 1295 with a serrated edge. This razor can be rotated manually by means of a catheter or controller tool 1285 attached during hand-off. The razor 1295 is completely contained within the thin-walled cylinder 1290 until actuated. The back of the cylinder is attached to a wire cage 1330 that streamlines the profile to facilitate insertion and removal of the debridement tool across the mitral valve, and supports a cup of filter material 1335 (shown schematically in Fig. 92 only) to capture the valve and valve debris liberated at the time of debridement. Coaxial to, and extending a few centimeters forward of, the cylinder is the transvalvular snout, or second handle, 1280. This consists of a thin-walled tube with multiple side fenestrations that is forced across the stenotic

valve. The multiple fenestrations allow the continued passage of blood across the orifice, without exacerbating the degree of stenosis or the outflow tract gradient.

The debridement tool is passed across the mitral valve on the beating heart. A catheter or controller tool 1285 based across the stenotic aortic valve (transvalvular catheter) is advanced into the left ventricular chamber, to effect an intra cardiac hand-off, as described previously. In one possible construction, the hand-off catheter 1285 is passed percutaneously, perhaps down the central lumen of a valve/filter assembly, also passed percutaneously.

Ideally, the snout 1280 of the debridement tool and the tip of the transvalvular catheter 1285 are both fitted with rare earth magnets or other appropriate structures so as to facilitate rapid reproducible alignment. Once aligned, the transvalvular catheter 1285 is actuated to achieve a mechanical coupling to allow the debridement tool to be pulled forcibly into position. The tool 1275 which

was initially used to pass the debridement tool across the mitral valve is then released and removed after mechanical coupling is accomplished, but before pulling the debridement tool into position across the stenotic valve.

Attached to the aforementioned snout 1280 is an umbrella 1300 comprised of rays (or struts of nitinol or other superelastic material) or other satisfactory material supporting a disk of filter material 1340 similar to that attached to the back of the debridement tool. The umbrella 1300 is designed so that it can be pulled across the stenotic valve in a closed configuration, from the ventricular side of the valve to the aortic side of the valve, and subsequently opened. The umbrella struts form a skeleton with a radius equal to that of the thin-walled cylinder 1290, and slightly greater than the cylindrical razor 1295. The disk of filter material has a radius that is somewhat greater than that of the thin-walled cylinder 1290. The umbrella struts may be attached to a ring that slides

longitudinally with respect to the snout. The transvalvular catheter, when actuated, causes both delivery of the umbrella to the aortic side of the valve as well as a configuration change from closed to open. The result is that the stenotic valve is impaled on the snout and wedged between the thin-walled cylinder on the ventricular side and the open umbrella on the aortic side.

In one embodiment, the umbrella 1300 is inverted. That is to say, when it is pulled across the stenotic valve, the apex of the umbrella is the first to pass, and the outer circumference of the umbrella tines and filter disk is last to pass. In this construction, the device is preferably spring-loaded so that when the tips of the tines clear the valve orifice and tension is released, the umbrella forms as a result of its own recoil against the aortic surface of the valve.

The geometry and construction of the debridement tool is such that it will orient coaxially with respect to the left ventricular outflow tract and the

valve orifice. Once the umbrella 1300 is deployed, the position is carefully inspected by echo and/or fluoroscopy. When correctly deployed, only a small gap exists between the disk and the thin-walled cylinder. It is therefore impossible to position and deploy the device with anything other than valvular tissue within this narrow gap. Only if the debridement tool was deployed at a significant angle, or was markedly undersized, could aortic or left ventricular tissue become pinched in this gap. Once it is confirmed that the debridement tool's position is correct, and the umbrella 1300 is deployed, the cylindrical razor 1295 is manually advanced and rotated, again under echo and/or fluoroscopic guidance, while maintaining tactile feedback by way of a rotating central element of the transvalvular catheter. It is not imperative that the valve be debrided in its entirety; rather, that a hole result that has edges suitable for the fixation mechanism, and that is large enough to allow fixation of the prosthesis, and that will relieve the outflow tract

gradient. As the fixation mechanism and the orifice of the prosthesis may not be co-planer in this application, the demands on debridement and orifice size may be considerably less than with a conventional prosthetic valve implantation.

As soon as the cylindrical serrated razor 1295 cuts through the last of the valvular tissue, there will be no tissue remaining to prevent the spring-loaded umbrella 1300 from retracting toward the thin-walled cylinder 1290, in effect snapping a lid on the cylinder with the valve remnants inside. Inasmuch as the umbrella 1300 and the cage 1330 at the back of the thin-walled cylinder are covered with filter material, the valve tissue cannot escape. Because the filter material is fairly transparent to blood, resistance to flow and cardiac emptying should not be significantly impacted by its presence in the left ventricular outflow tract. A single-use serrated cylindrical razor 1295, with teeth of an appropriately small size, when used in a proper fashion (multiple small amplitude rotations while applying minimal

force) will be able to cut a smooth round hole out of even the most calcified and thickened valve.

Once the umbrella is seen (by echo and/or fluoro) to have snapped down on the cylinder, the inference is made that the valve has been completely excised. Valvular competence at this point is provided entirely by the down-stream valve, an embodiment of which is described as the valved arch filter (see U.S. Provisional Patent Application Serial No. 60/425,877, filed 11/13/02 by William E. Cohn for CARDIAC VALVE PROCEDURE METHODS AND DEVICES, Attorney's Docket No. VIA-41 PROV, which patent application is hereby incorporated herein by reference). Any particulate material that escapes the debridement tool is prevented from embolizing by this down-stream filter.

The closed debridement tool, with the valve remnants inside, is then passed back across the mitral valve and removed through the left atrial blood-lock.

It should also be appreciated that a valve debridement tool may also comprise a laser, an ultrasonic device, a rotary drill bit, an auger, or

any other mechanism that appropriately disrupts tissue.

Furthermore, the valve debridement tool can be passed down the aorta, through the valve and across to the ventricular side for deployment and retrograde cutting.

Preferably the valve debridement tool is formed so as to be selectively collapsible, whereby it may be advanced to the surgical site through a catheter, e.g., by a catheter introduced through a peripheral artery.

What Is Claimed Is:

1. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a first frame member and a second frame member configured in opposition to one another;

a cutting edge configured on the first frame member;

an adjustable connector positionably joining the first frame member to the second frame member, the adjustable connector configured to selectively position the first frame member and the second frame member between a first position and a second position, wherein the first frame member and the second frame member are positioned apart from one another in the first position so as to allow at least a portion of the diseased heart valve therebetween, and the first frame member and the second frame member are positioned together in the second position so as to cut the at least a portion of the diseased heart valve

therebetween with the cutting blade so as to resect the diseased heart valve;

an actuator configured in operable connection to the adjustable connector, the actuator configurable to selectively position the adjustable connector between the first position and the second position; and

a first screen portion and a second screen portion disposed on the first frame portion and the second frame portion, respectively, the first screen portion and the second screen portion configured to allow blood flow through first frame member and second frame member and to contain the at least a portion of the diseased heart valve between the first frame member and the second frame member.

2. Apparatus according to claim 1 wherein the adjustable connector further comprises a spring configured to bias the first frame portion and the second frame portion into the second position.

3. Apparatus according to claim 1 wherein the adjustable connector comprises a threadable connection with one of the first frame member and the second frame member so as to allow the adjustable connector to selectively position the first frame member and the second frame member between the first position and the second position using a twisting motion for the actuator.

4. Apparatus according to claim 1 wherein the second frame member comprises a cutting edge configured thereon, and further wherein the cutting edge of the first frame member and the cutting edge of the second frame member each comprise cutting teeth configured for rotatable engagement with one another, and the actuator is configured for selective rotation and engagement of the first frame member and the second frame member relative to one another so as to cut the at least a portion of the diseased heart valve disposed therebetween.

5. Apparatus according to claim 1 wherein one of the first frame member and the second frame member is mounted to a screw-driven assembly so as to rotate the one of the first frame member and the second frame member mounted to the screw-driven assembly to aid in cutting the diseased heart valve therebetween.

6. A method of resecting a diseased heart valve, the method comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a first frame member and a second frame member configured in opposition to one another;

a cutting edge configured on the first frame member;

an adjustable connector positionably joining the first frame member to the second frame member, the adjustable connector configured to selectively position the first frame member and the second frame member between a first position and a second position, wherein the first frame member and the second frame

member are positioned apart from one another in the first position so as to allow at least a portion of the diseased heart valve therebetween, and the first frame member and the second frame member are positioned together in the second position so as to cut the at least a portion of the diseased heart valve therebetween with the cutting blade so as to resect the diseased heart valve;

an actuator configured in operable connection to the adjustable connector, the actuator configurable to selectively position the adjustable connector between the first position and the second position; and

a first screen portion and a second screen portion disposed on the first frame portion and the second frame portion, respectively, the first screen portion and the second screen portion configured to allow blood flow through first frame member and second frame member and to contain the at least a portion of the diseased heart valve between the first frame member and the second frame member;

positioning the first frame member and the second frame member on opposed sides of the diseased heart valve, with the first frame member and the second frame member in the first position;

closing the first frame member and the second frame member from the first position to the second position by manipulating the actuator in operable connection to the adjustable connector so as to move the cutting edge through the at least a portion of the diseased heart valve; and

removing from a patient the first frame member and the second frame member closed together in the second position, with the at least a portion of the diseased heart valve therebetween.

7. A method according to claim 6 wherein the first frame member and the second frame member are advanced through a chamber of the heart to the diseased heart valve.

8. A method according to claim 6 wherein the diseased heart valve comprises an aortic valve, and further wherein the first frame member and the second frame member are advanced through the aorta to the aortic valve.

9. A method of resecting a diseased heart valve, the method comprising:

positioning a first frame member and a second frame member on opposed sides of the diseased heart valve, with the first frame member and the second frame member positioned apart from one another;

closing the first frame member and the second frame member toward one another so as to pass a cutting edge disposed on the first frame member through at least a portion of the diseased heart valve; and

removing from the patient the first frame member and the second frame member closed together, with the at least a portion of the diseased heart valve therebetween.

10. A method according to claim 9 wherein the first frame member and the second frame member are advanced to the diseased heart valve through a chamber of a heart.

11. A method according to claim 9 wherein the diseased heart valve comprises an aortic valve, and further wherein the first frame member and the second frame member are advanced through the aorta to the aortic valve.

12. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a power shaver having a proximal end and a distal end, the power shaver defining a longitudinal axis from the proximal end to the distal end, and a cutting element disposed adjacent to the distal end of the power shaver; and

a power shaver guide having a first end and a second end in opposition to one another, the power

shaver guide defining a first opening extending into the first end, the first opening defining a first axis from the first end of the power shaver guide to the second end of the power shaver guide, the first opening configured to receive a portion of the power shaver therein, the power shaver guide having a given width from the first opening to an outer surface in a direction perpendicular to the first axis, the given width of the power shaver guide configured to prevent the wall of a cardiovascular structure from being cut by the power shaver disposed within the first opening and to permit the power shaver to be placed within the diseased valve.

13. Apparatus according to claim 12 wherein a lateral surface of the power shaver guide further defines a second hole therein, the second hole extending between the lateral surface of the power shaver guide and the first hole so as to allow cutting of the diseased valve by the power shaver through the second hole.

14. Apparatus according to claim 12 wherein the first opening extends from the first end of the power shaver guide through the second end of the power shaving guide so as to allow placement of the distal end of the power shaver into the first opening through the first end and the second end, with the cutting element disposed adjacent to the second end of the power shaver guide.

15. Apparatus according to claim 12 wherein the power shaver guide comprises a rigid ring forming a blood flow passageway parallel to the first axis.

16. Apparatus according to claim 12 wherein the power shaver guide comprises a collapsible portion.

17. Apparatus according to claim 16 wherein the collapsible portion comprises an inflatable balloon.

18. A method for resecting a diseased heart valve comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a power shaver having a proximal end and a distal end, the power shaver defining a longitudinal axis from the proximal end to the distal end, and a cutting element disposed adjacent to the distal end of the power shaver; and

a power shaver guide having a first end and a second end in opposition to one another, the power shaver guide defining a first opening extending into the first end, the first opening defining a first axis from the first end of the power shaver guide to the second end of the power shaver guide, the first opening configured to receive a portion of the power shaver therein, the power shaver guide having a given width from the first opening to an outer surface in a direction perpendicular to the first axis, the given width of the power shaver guide configured to prevent the wall of a cardiovascular structure from being cut

by the power shaver disposed within the first opening and to permit the power shaver to be placed within the diseased valve;

positioning the power shaver within the power shaving guide;

positioning the power shaver and power shaving guide through a cardiovascular structure to the diseased heart valve; and

cutting the diseased valve with the cutting element of the power shaver so as to resect the diseased heart valve.

19. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a set of at least three expandable arms having a proximal end and a distal end in opposition to one another, the set of expandable arms defining a longitudinal axis from the proximal end to the distal end;

a first restraining element and a second restraining element configured at the proximal end of

the set of expandable arms and the distal end of the set of at least three expandable arms, respectively, the first restraining element and the second restraining element configured to selectively position the set of at least three expandable arms between a first position and a second position, the set of at least three expandable arms having a given width in a perpendicular direction to the longitudinal axis at the first position and having a larger width in the perpendicular direction to the longitudinal axis at the second position; and

a cutting device disposed on at least one of the at least three expandable arms, the cutting device configured to cut through the diseased heart valve.

20. Apparatus according to claim 19 wherein the cutting device comprises a wire.

21. Apparatus according to claim 20 wherein the wire is rotary driven.

22. Apparatus according to claim 20 wherein the wire is reciprocally driven.

23. Apparatus according to claim 20 wherein the at least one of the at least three expandable arms having the cutting device disposed thereon defines a window recess therein having a given depth from an outer surface, and further wherein the cutting device is disposed in the window recess.

24. Apparatus according to claim 20 wherein the wire comprises a rough surface.

25. Apparatus according to claim 20 wherein the wire comprises an electrocautery element.

26. Apparatus according to claim 19 wherein the cutting device comprises a power shaver.

27. A method for resecting a diseased heart valve, the apparatus comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a set of at least three expandable arms having a proximal end and a distal end in opposition to one another, the set of expandable arms defining a longitudinal axis from the proximal end to the distal end;

a first restraining element and a second restraining element configured at the proximal end of the set of expandable arms and the distal end of the set of at least three expandable arms, respectively, the first restraining element and the second restraining element configured to selectively position the set of at least three expandable arms between a first position and a second position, the set of at least three expandable arms having a given width in the perpendicular direction to the longitudinal axis at the first position and having a larger width in the perpendicular direction to the longitudinal axis at the second position; and

a cutting device disposed on at least one of the at least three expandable arms, the cutting device configured to cut through the diseased heart valve;

positioning the set of at least three expandable arms adjacent to the diseased heart valve;

expanding the set of at least three expandable arms from the first position to the second position; and

cutting the diseased heart valve with the cutting device disposed on the at least one of the at least three expandable arms.

28. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a first frame member and a second frame member configured in opposition to one another;

a cutting edge configured on the first frame member;

an adjustable connector positionably joining the first frame member to the second frame member, the adjustable connector configured to selectively

position the first frame member and the second frame member between a first position and a second position, wherein the first frame member and the second frame member are positioned apart from one another in the first position so as to allow at least a portion of the diseased heart valve therebetween, and the first frame member and the second frame member are positioned together in the second position so as to cut the at least a portion of the diseased heart valve therebetween with the cutting blade so as to resect the diseased heart valve;

an actuator configured in operable connection to the adjustable connector, the actuator configurable to selectively position the adjustable connector between the first position and the second position; and

at least two spikes extending from the first frame member toward the second frame member, the at least two spikes being configured to pierce and secure leaflets of the diseased heart valve as the first frame member and the second frame member are positioned toward one another.

29. Apparatus according to claim 28 wherein the second frame member defines a cavity configured to receive at least one of the at least two spikes therein.

30. Apparatus according to claim 28 further comprising at least two additional spikes extending from the second frame member, the at least two additional spikes being configured to pierce and hold in place the leaflets of the diseased heart valve as the first frame member and the second frame member are positioned toward one another.

31. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a catheter having a proximal end and a distal end, the catheter defining a longitudinal axis from the proximal end to the distal end; and

a set of blades positionably configurable at the distal end of the catheter, a hinge mechanism holding

the distal end of the set of blades together, and a control rod extending from the proximal end of the blades into the catheter, the control rod being configured to selectively position the set of blades from a first position within the catheter to a second position outside of the distal end of the catheter, to selectively expand the set of blades from a narrow width for disposition within the catheter to a wide width for cutting portions of the diseased heart valve with the set of blades, and to rotate the set of blades with respect to the longitudinal axis of the catheter.

32. Apparatus according to claim 31 further comprising a filter mounted on the hinge mechanism.

33. Apparatus according to claim 31 wherein the blades comprise serrated portions so as to aid in cutting through the diseased heart valve.

34. A method of resecting a diseased heart valve, the method comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a catheter having a proximal end and a distal end, the catheter defining a longitudinal axis from the proximal end to the distal end; and

a set of blades positionably configurable at the distal end of the catheter, a hinge mechanism holding the distal end of the set of blades together, and a control rod extending from the proximal end of the blades into the catheter, the control rod being configured to selectively position the set of blades from a first position within the catheter to a second position outside of the distal end of the catheter, to selectively expand the set of blades from a narrow width for disposition within the catheter to a wide width for cutting portions of the diseased heart valve with the set of blades, and to rotate the set of blades with respect to the longitudinal axis of the catheter;

placing distal end of the catheter adjacent to the diseased heart valve;

positioning the set of blades from the first position within the catheter to the second position outside of the distal end of the catheter;

expanding the set of blades from the narrow width for disposition within the catheter to the wide width for cutting portions of the diseased heart valve with the set of blades; and

rotating the set of blades with respect to the longitudinal axis of the catheter so as to cut through the diseased heart valve.

35. A method according to claim 34 further comprising a filter mounted on the hinge mechanism, and further comprising the step of closing the set of blades to capture portions of the resected heart valve in the filter.

36. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a catheter having a proximal end and a distal end, and the catheter defining a longitudinal axis from the proximal end to the distal end;

a control rod having a proximal end and a distal end, the control rod being selectively positionable through the catheter and being selectively rotatable with respect to the longitudinal axis of the catheter;

an outer shell portion having a first edge and a second edge in opposition to one another, the outer shell portion having an inwardly facing side and an outwardly facing side in opposition to one another, the first edge of the outer shell portion being attached to the control rod along a surface thereof parallel to the longitudinal axis of the catheter, and the outer shell portion adapted to be wound around the control rod; and

a spring having a first end and a second end, the first end of the spring being attached to the inwardly facing side of the outer shell portion adjacent to the second edge thereof, and the spring being disposed

against the inwardly facing side of the outer shell portion;

wherein rotation of the control rod in a first direction in combination with a force applied by the spring contracts the outer shell portion toward the control rod so as to reduce a maximum outer diameter of the outer shell in a given direction perpendicular to the longitudinal axis of the catheter, and rotation of the control rod in a second direction in combination with the force applied by the spring rolls the outer shell portion away from the control rod so as to expand the maximum outer diameter of the outer shell portion in the given direction perpendicular to the longitudinal axis of the catheter.

37. Apparatus according to claim 36 further comprising another outer shell portion disposed on the control rod at a location proximal to the outer shell portion, and further wherein the control rod between the outer shell portion and the another outer shell portion is adjustable to selectively open and close

together the outer shell portion and the another outer shell portion.

38. Apparatus according to claim 37 wherein the outer shell portion and the another shell portion each have a cutting edge in opposition to one another.

39. A method for resecting a diseased heart valve, the method comprising:

providing apparatus for resecting a diseased heart valve, the apparatus comprising:

a catheter having a proximal end and a distal end, and the catheter defining a longitudinal axis from the proximal end to the distal end;

a control rod having a proximal end and a distal end, the control rod being selectively positionable through the catheter and being selectively rotatable with respect to the longitudinal axis of the catheter;

an outer shell portion having a first edge and a second edge in opposition to one another, the

outer shell portion having an inwardly facing side and an outwardly facing side in opposition to one another, the first edge of the outer shell portion being attached to the control rod along a surface thereof parallel to the longitudinal axis of the catheter, and the outer shell portion adapted to be wound around the control rod; and

a spring having a first end and a second end, the first end of the spring being attached to the inwardly facing side of the outer shell portion adjacent to the second edge thereof, and the spring being disposed against the inwardly facing side of the outer shell portion;

positioning the distal end of the catheter adjacent to the diseased heart valve;

rotating the control rod in the second direction so as to expand the outer shell portion; and

withdrawing the apparatus from the human body.

40. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a tubular body having a proximal end and a distal end, the tubular body defining a longitudinal axis from the proximal end to the distal end; and

an auger blade disposed within the tubular body and configured to selectively rotate with respect to the longitudinal axis of the tubular body;

the tubular body defining an opening configured therein so as to allow portions of the diseased heart valve therein, and the opening defining a junction region at a location where the auger blade contacts the tubular body and cuts the portions carried by the auger blade thereto.

41. Apparatus according to claim 40 wherein the auger blade and the tubular body are configured to carry the cut portions of the heart valve through the distal end of the tubular body away from the opening.

42. Apparatus according to claim 40 wherein the tubular body further comprises a set of guide shields positioned adjacent to the opening into the auger

blade so as to prevent cutting surrounding cardiovascular structure.

43. A method for resecting a diseased heart valve, the method comprising:

positioning an opening of a tubular body adjacent to the diseased heart valve; and

cutting the diseased heart valve with an auger blade rotating within the tubular body.

44. Apparatus for resecting a diseased heart valve, the apparatus comprising:

an inner rod having a proximal end and a distal end, the inner rod defining a longitudinal axis from the proximal end to the distal end, and the inner rod defining a first opening and a second opening in a lateral side thereof between the proximal end and the distal end;

a first outer shell and a second outer shell each having a selectively configurable length through the first opening and the second opening of the inner rod,

respectively, the first outer shell and the second outer shell configured to be radially expandable depending on the length of the first outer shell and the second outer shell configured through the first opening and the second opening, respectively; and

a blade extending between the first outer shell and the second outer shell, the blade being radially expandable away from the inner rod together with the first outer shell.

45. Apparatus for resecting a diseased heart valve, the apparatus comprising:

an inner cylinder having an outer tube rotatably disposed thereto, the inner cylinder and outer tube having a distal end and a proximal end, and the inner cylinder defining a longitudinal axis from the distal end to the proximal end;

at least one barb extending away from the distal end of the inner cylinder; and

three blades pivotally attached to the distal end of the outer tube, the three blades being selectively

configurable in a first position and a second position, the first position configured with the blades closed toward one another so as to cover the at least one barb and provide a narrow cross-section therethrough in a perpendicular direction to the longitudinal axis, and a second position configured with the blades opened away from one another so as to expose the at least one barb and provide a cutting diameter having a greater cross-section therethrough than the narrow cross-section in the perpendicular direction to the longitudinal axis;

wherein the three blades are positioned closed toward one another through a body to a location adjacent to a diseased heart valve, the three blades are opened away from one another so as to expose the at least one barb extending away from the distal end of the inner cylinder, the inner cylinder is positioned toward the diseased heart valve so as to spear the at least one barb therethrough, and the outer tube is rotated around the inner cylinder so as to rotate the three blades to cut the diseased valve.

46. Apparatus according to claim 45 wherein the three blades are configured to cut at forward sections thereof, respectively.

47. Apparatus according to claim 45 wherein the three blades are configured to cut at side sections thereof, respectively.

48. Apparatus according to claim 45 further comprising a filter extending away from the distal end of the inner cylinder, the filter being configured to contain portions of the diseased heart valve cut away from a body of a patient.

49. A method for resecting a diseased heart valve, the method comprising:

providing apparatus for resecting a diseased heart valve, the apparatus comprising:

an inner cylinder having an outer tube rotatably disposed thereto, the inner cylinder and

outer tube having a distal end and a proximal end, and the inner cylinder defining a longitudinal axis from the distal end to the proximal end;

at least one barb extending away from the distal end of the inner cylinder; and

three blades pivotally attached to the distal end of the outer tube, the three blades being selectively configurable in a first position and a second position, the first position configured with the blades closed toward one another so as to cover the at least one barb and provide a narrow cross-section thereto in a perpendicular direction to the longitudinal axis, and a second position configured with the blades opened away from one another so as to expose the at least one barb and provide a cutting diameter having a greater cross-section therethrough than the narrow cross-section in the perpendicular direction to the longitudinal axis;

wherein the three blades closed toward one another through a body to a location are positioned adjacent to a diseased heart valve, the three blades

are opened away from one another so as to expose the at least one barb extending away from the distal end of the inner cylinder, the inner cylinder is positioned toward the diseased heart valve so as to spear the at least one barb therethrough, and the outer tube is rotated around the inner cylinder so as to rotate the three blades to cut the diseased valve;

positioning the three blades toward the diseased heart valve;

opening the three blades away from one another so as to expose the at least one barb;

spearing the at least one barb through the diseased heart valve; and

rotating the three blades so as to cut the diseased valve.

50. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a chamber having a proximal end and a distal end, and a sidewall extending between the proximal end and the distal end;

a retractable barb selectively positionable between a first position and a second position, the retractable bar being configured within the distal end of chamber in the first position, and the retractable bar being configured to extend beyond the distal end of the chamber in the second position; and

a set of blades surrounding the distal end of the chamber;

wherein the retractable barb extends from the chamber, pierces a portion of the diseased heart valve, and retracts into the chamber; and

wherein the set of blades cuts through the portion of the diseased heart valve pierced by the retractable barb as the retractable barb retracts into the chamber.

51. Apparatus according to claim 50 wherein the set of blades rotates around the retractable barb so as to cut through the portion of the diseased heart valve pierced by the retractable barb as the retractable barb retracts into the chamber.

52. Apparatus according to claim 50 wherein the cylinder rotates around the retractable barb so as to cut through the portion of the diseased heart valve pierced by the retractable barb as the retractable barb retracts into the chamber.

53. A method for resecting a diseased heart valve, the method comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a chamber having a proximal end and a distal end, and a sidewall extending between the proximal end and the distal end;

a retractable barb selectively positionable between a first position and a second position, the retractable bar being configured within the distal end of chamber in the first position, and the retractable bar being configured to extend beyond the distal end of the chamber in the second position; and

a set of blades surrounding the distal end of the chamber;

wherein the retractable barb extends from the chamber, pierces a portion of the diseased heart valve, and retracts into the chamber; and

wherein the set of blades cuts through the portion of the diseased heart valve pierced by the retractable barb as the retractable barb retracts into the chamber;

positioning the distal end of the chamber adjacent to the diseased heart valve;

extending the retractable barb from the chamber;

piercing the portion of the diseased heart valve with the retractable barb;

retracting the retractable barb into the chamber; and

cutting through the portion of the diseased heart valve pierced by the retractable barb with the set of blades.

54. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a body portion having a proximal end and a distal end, the body portion defining a longitudinal axis from the proximal end to the distal end, and the body portion defining an opening at the distal end thereof;

a grasping tool being selectively positionable within the body portion along the longitudinal axis from a first position to a second position, the grasping tool being configured within the body portion in the first position, the grasping tool extending through the opening at the distal end of the body portion in the second position, and the grasping tool being configured to selectively close together a first portion and a second portion so as to selectively grip the diseased heart valve therebetween; and

a cutting element disposed within the body portion at a given distance from the opening, the cutting element configured to close together to cut the diseased heart valve therebetween at the given distance from the opening after the grasping tool is

withdrawn to a given location between the cutting element and the proximal end of the body portion;

wherein a portion of the diseased heart valve portion cut away from an intact portion of the diseased heart valve is contained within the body portion.

55. A method of resecting a diseased heart valve, the method comprising:

providing apparatus for resecting the diseased heart valve, the apparatus comprising:

a body portion having a proximal end and a distal end, the body portion defining a longitudinal axis from the proximal end to the distal end thereof, and the body portion defining an opening at the distal end;

a grasping tool being selectively positionable within the body portion along the longitudinal axis from a first position to a second position, the grasping tool being configured within the body portion in the first position, the grasping

tool extending through the opening at the distal end of the body portion, and the grasping tool being configured to selectively close together a first portion and a second portion so as to selectively grip the diseased heart valve therebetween; and

a cutting element disposed within the body portion at a given distance from the opening, the cutting element configured to close together to cut the diseased heart valve therebetween at the given distance from the opening after the grasping tool is withdrawn to a given location between the cutting element and the proximal end of the body portion;

wherein a portion of the diseased heart valve portion cut away from an intact portion of the diseased heart valve is contained within the body portion;

positioning the distal end of the body portion adjacent to the diseased heart valve;

extending the grasping tool through the opening in the body portion to the diseased heart valve portion;

closing the first portion and the second portion of the grasping tool toward one another so as to secure a portion of the diseased heart valve therebetween;

retracting the grasping tool into the body element past the cutting element to the given location between the cutting element and the proximal end of the body portion so as to allow the cutting element to close and cut the portion of the diseased heart valve at the given distance from the opening.

56. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a body portion having a first end and a second end in opposition to one another, a lateral wall extending from the first end to the second end, the lateral wall defining an inner surface and an outer surface in opposition to one another, the inner surface and the outer surface defining arcuate surfaces, respectively, and the body portion defining

a longitudinal axis from the first end to the second end;

a first handle and a second handle attached to the body portion to extend from the first end thereof and the second end thereof, respectively;

a cutting blade selectively rotatable about the longitudinal axis and disposed adjacent to the inner surface of the body portion;

a set of retaining arms positionably mounted between the second handle and the second end of the body portion, the set of retaining arms being selectively positionable from a contracted state to an expanded state, the contracted state forming a first diameter having a first width in a direction perpendicular to the longitudinal axis of the body portion, the expanded state forming a second diameter having a second width in a direction perpendicular to the longitudinal axis of the body portion, the second width being larger than a first width of the first diameter in the direction perpendicular to the longitudinal axis of the body portion;

a pass-off tool having a proximal end and a distal end, a first attachment device at the distal end thereof, the first attachment device configured to selectively engage the first handle attached to the body portion so as to allow placement of the second handle of the body portion adjacent to the diseased heart valve; and

a controller tool having a proximal end and a distal end, a second attachment device at the distal end thereof, the second attachment device configured to selectively engage the second handle attached to the body portion so as to allow positioning of the second end of the body portion adjacent to the diseased heart valve, a cutting blade actuator configured to cause the cutting blade to selectively rotate relative to the longitudinal axis of the body portion, and a retaining arm actuator configured to selectively position the set of retaining arms from the contracted state to the expanded state.

57. Apparatus according to claim 56 further comprising a cage structure extending away from the first end of the body portion, the cage structure being configured to hold the cut portion of the diseased heart valve within the body portion.

58. Apparatus according to claim 56 further comprising a first filter material at the first end of the body portion, the first filter material being configured to hold the cut portion of the diseased heart valve within the body portion.

59. Apparatus according to claim 56 further comprising a second filter material disposed on the set of retaining arms, the second filter material being configured to hold the cut portion of the diseased heart valve within the body portion.

60. Apparatus according to claim 56 wherein the cutting blade comprises a serrated cylindrical razor.

61. Apparatus according to claim 56 wherein the cutting blade is configured for selective advancement from the second end of the body portion.

62. Apparatus according to claim 56 wherein the body portion is advanced to the diseased heart valve through a chamber of a heart.

63. Apparatus according to claim 56 wherein the body portion is advanced to the diseased heart valve through the aorta.

64. A method for resecting a diseased heart valve, the method comprising:

providing apparatus for resecting a diseased heart valve, the apparatus comprising:

a body portion having a first end and a second end in opposition to one another, a lateral wall extending from the first end to the second end, the lateral wall defining an inner surface and an outer surface in opposition to one another, the inner

surface and the outer surface defining arcuate surfaces, respectively, and the body portion defining a longitudinal axis from the first end to the second end thereof;

a first handle and a second handle attached to the body portion to extend from the first end thereof and the second end, respectively;

a cutting blade selectively rotatable about the longitudinal axis and disposed adjacent to the inner surface of the body portion;

a set of retaining arms positionably mounted between the second handle and the second end of the body portion, the set of retaining arms being selectively positionable from a contracted state to an expanded state, the contracted state forming a first diameter having a first width in a direction perpendicular to the longitudinal axis of the body portion, the expanded state forming a second diameter having a second width in a direction perpendicular to the longitudinal axis of the body portion, the second width being larger than a first width of the first

diameter in the direction perpendicular to the longitudinal axis of the body portion;

a pass-off tool having a proximal end and a distal end, a first attachment device at the distal end thereof, the first attachment device configured to selectively engage the first handle attached to the body portion so as to allow placement of the second handle of the body portion adjacent to the diseased heart valve; and

a controller tool having a proximal end and a distal end, a second attachment device at the distal end thereof, the second attachment device configured to selectively engage the second handle attached to the body portion so as to allow positioning of the second end of the body portion adjacent to the diseased heart valve, a cutting blade actuator configured to cause the cutting blade to selectively rotate relative to the longitudinal axis of the body portion, and a retaining arm actuator configured to selectively position the set of retaining arms from the contracted state to the expanded state;

engaging the first handle attached to the body portion with the pass-off tool;

positioning the second handle of the body portion adjacent to the diseased heart valve;

engaging the second handle attached to the body portion with the controller tool;

disengaging the pass-off tool and the first handle from one another;

positioning the second end of the body portion adjacent to the diseased heart valve;

expanding the set of retaining arms with the retaining arm actuator so as to hold the cut portion of the diseased heart valve within the body portion;

rotating the cutting blade relative to the longitudinal axis of the body portion with the cutting blade actuator;

positioning the body portion toward the diseased heart valve with the controller tool so as to cut the diseased heart valve.

65. A method according to claim 64 further comprising:

repositioning and re-engaging the first handle to the pass-off tool;

disengaging the controller tool from the second handle; and

removing the body portion with the pass-off tool.

66. Apparatus for resecting a diseased heart valve, the apparatus comprising:

a cylindrical body portion having a first end and a second end;

a first handle and a second handle attached to the body portion to extend from the first end thereof and the second end thereof, respectively;

a cylindrical cutting blade selectively rotatable about the longitudinal axis and disposed within the body portion;

a set of retaining arms positionably mounted therebetween the second handle and the second end of the body portion, the set of retaining arms being

selectively positionable from a contracted state to an expanded state, the contracted state forming a first diameter having a first width in a direction perpendicular to the longitudinal axis of the body portion, the expanded state forming a second diameter having a second width in a direction perpendicular to the longitudinal axis of the body portion, the second width being larger than a first width of the first diameter in the direction perpendicular to the longitudinal axis of the body portion.

67. Apparatus according to claim 66 further comprising a pass-off tool having a proximal end and a distal end, a first attachment device at the distal end thereof, the first attachment device configured to selectively engage the first handle attached to the body portion so as to allow placement of the second handle of the body portion adjacent to the diseased heart valve.

68. Apparatus according to claim 66 further comprising a controller tool having a proximal end and a distal end, a second attachment device at the distal end thereof, the second attachment device configured to selectively engage the second handle attached to the body portion so as to allow positioning of the second end of the body portion adjacent to the diseased heart valve, a cutting blade actuator configured to cause the cutting blade to selectively rotate relative to the longitudinal axis of the body portion, and a retaining arm actuator configured to selectively position the set of retaining arms from the contracted state to the expanded state.

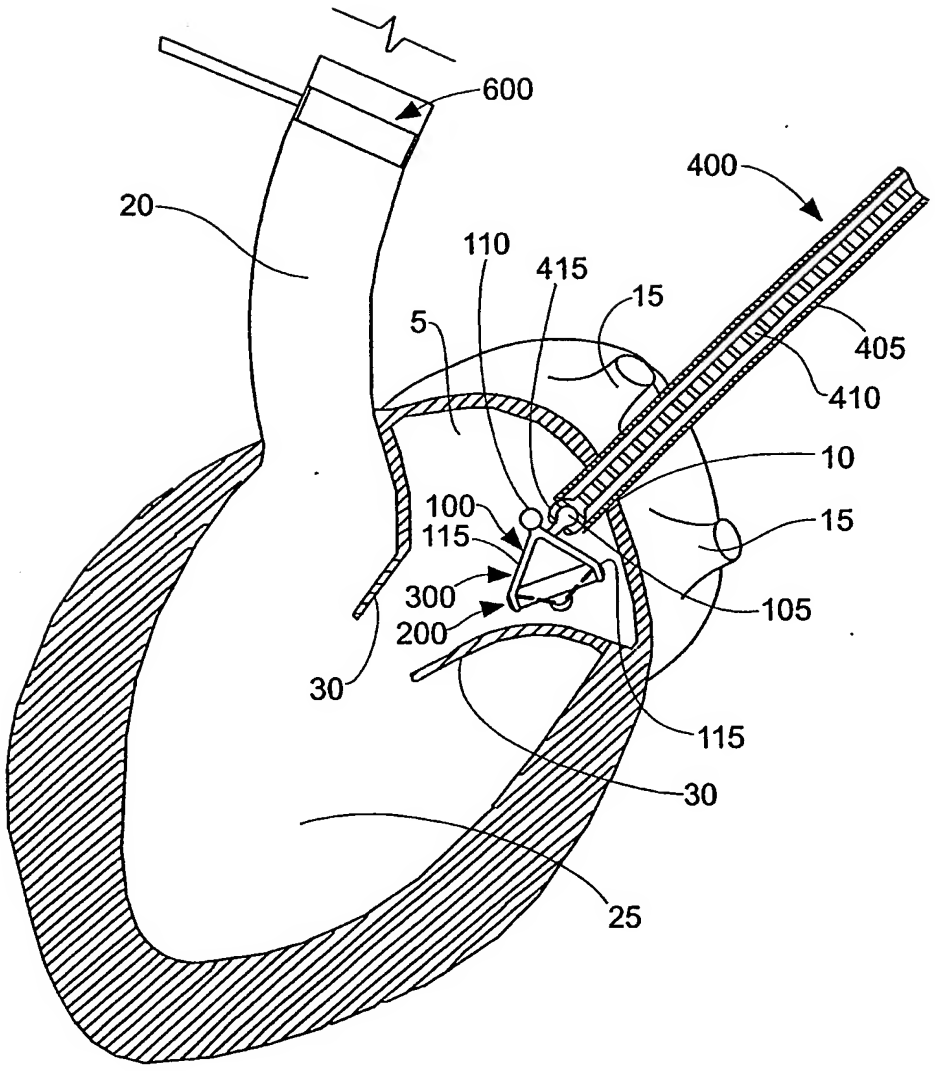
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FIG. 1

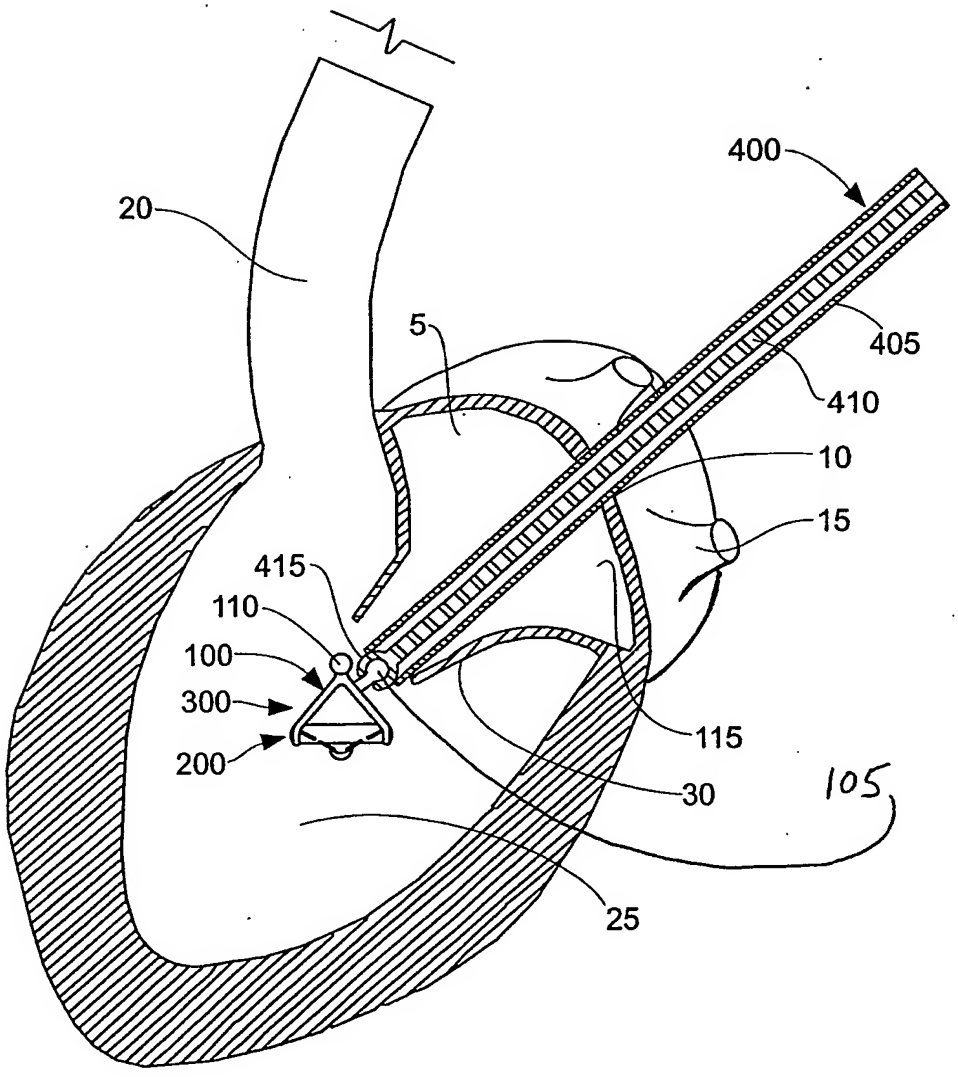

FIG. 2

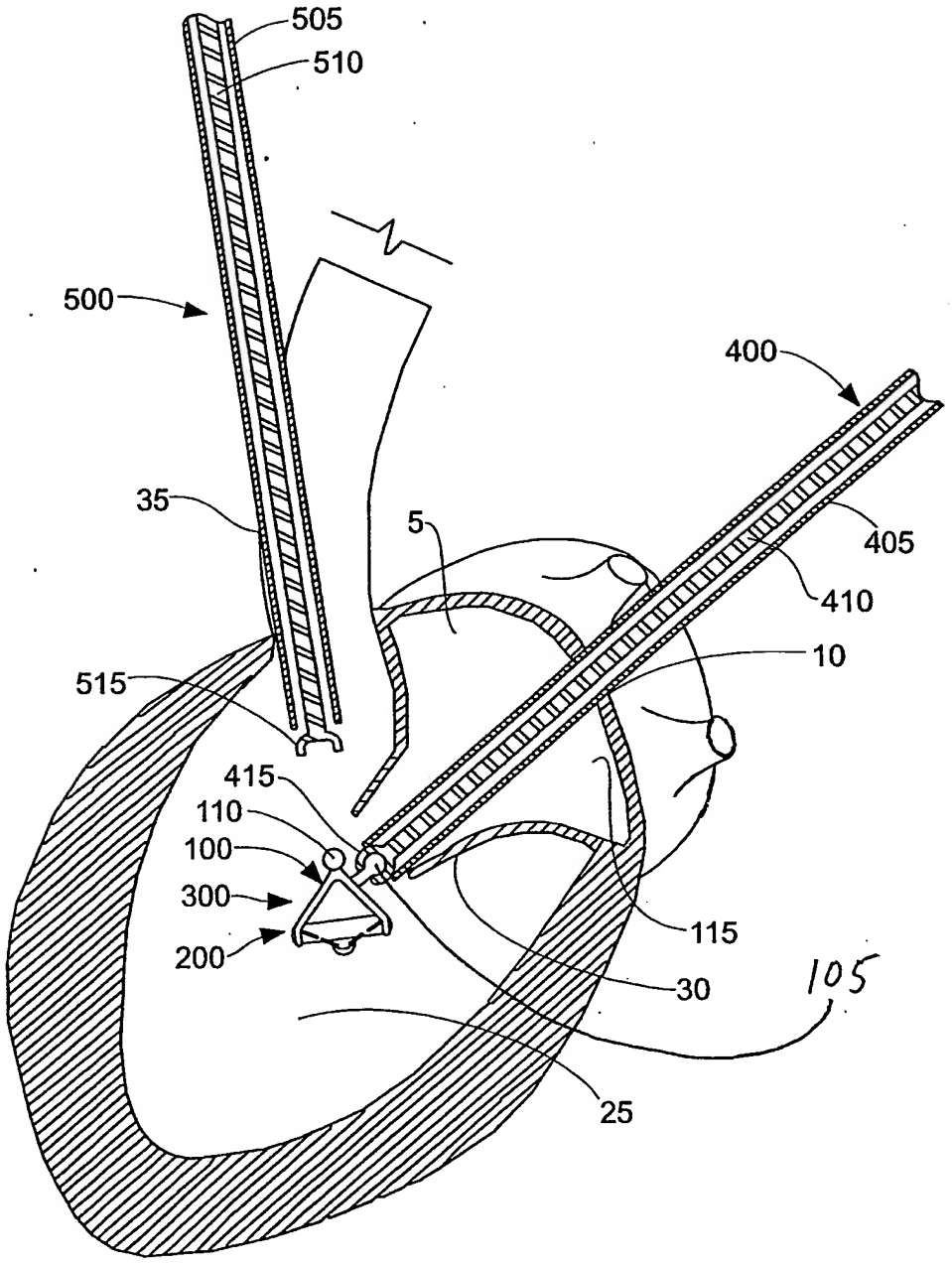
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FIG. 3

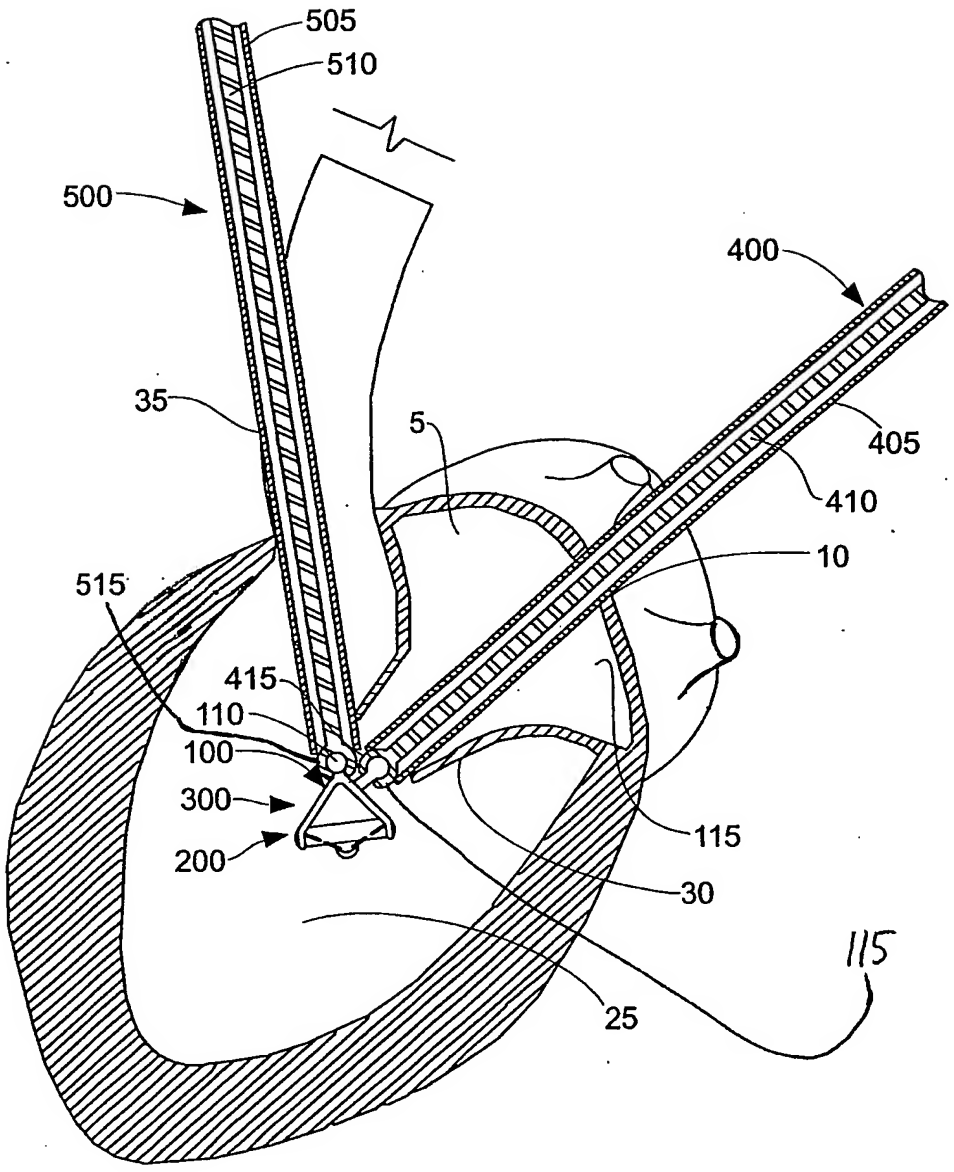
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FIG. 4

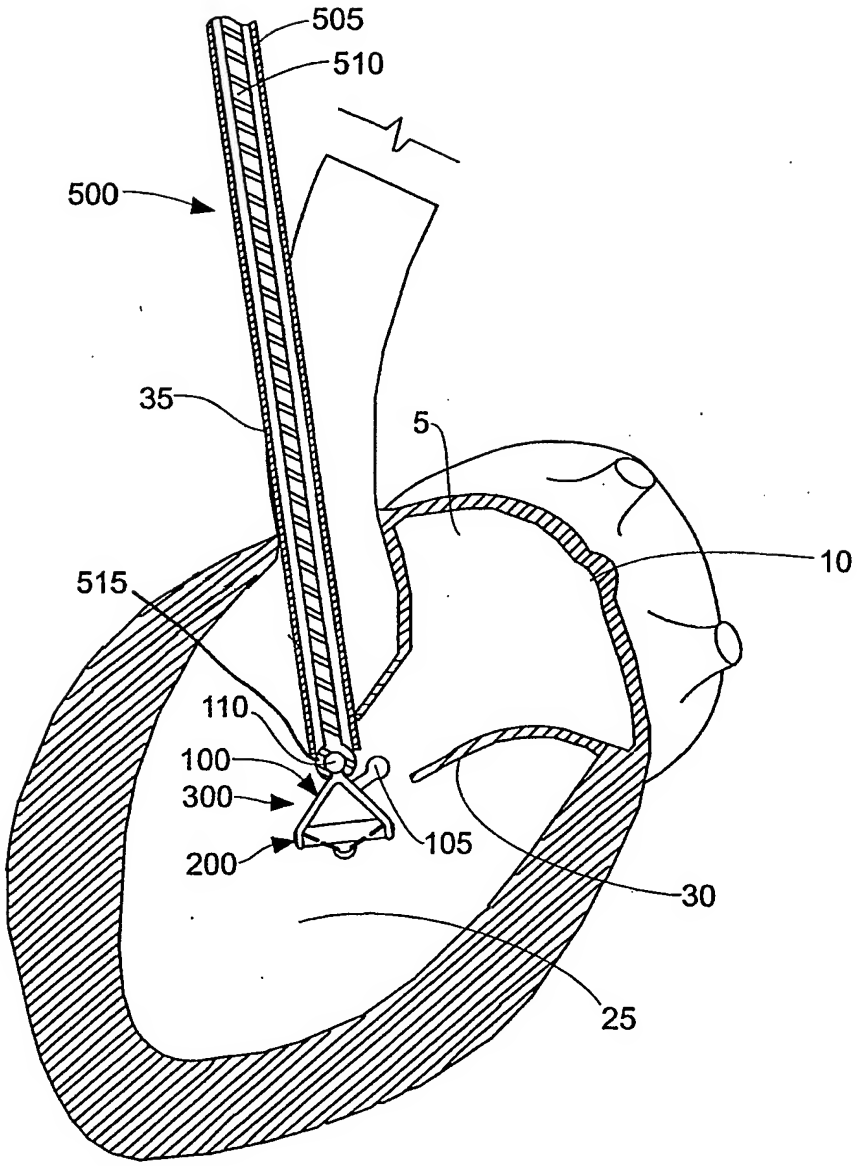

FIG. 5

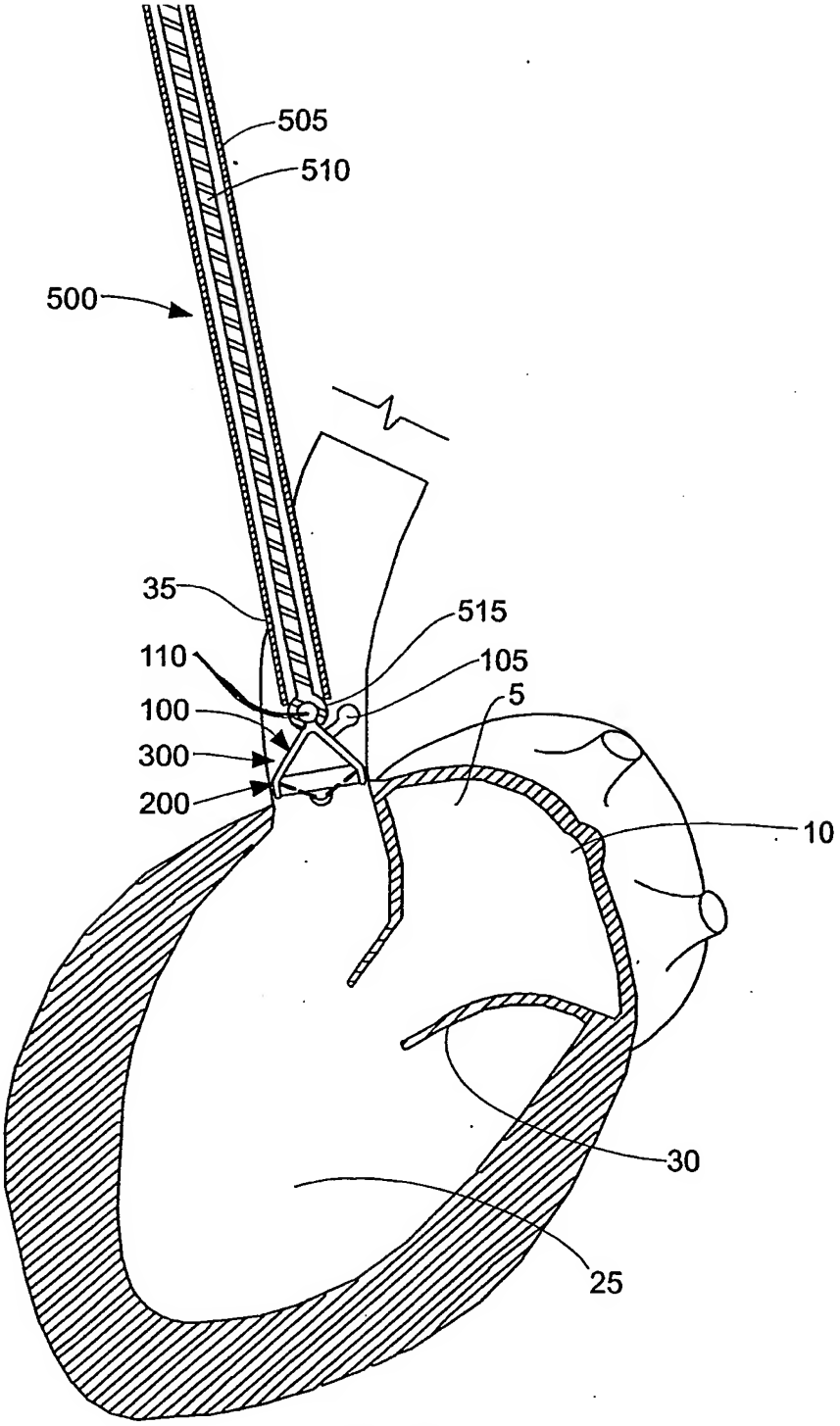

FIG. 6

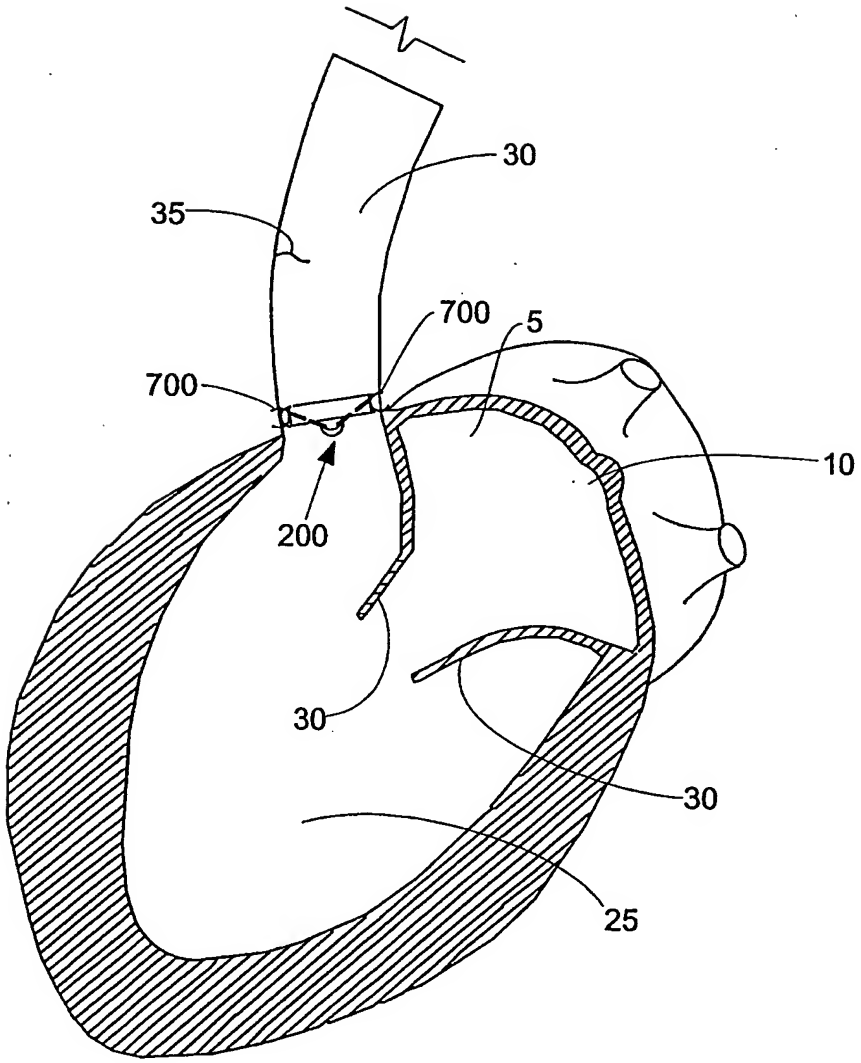

FIG. 7

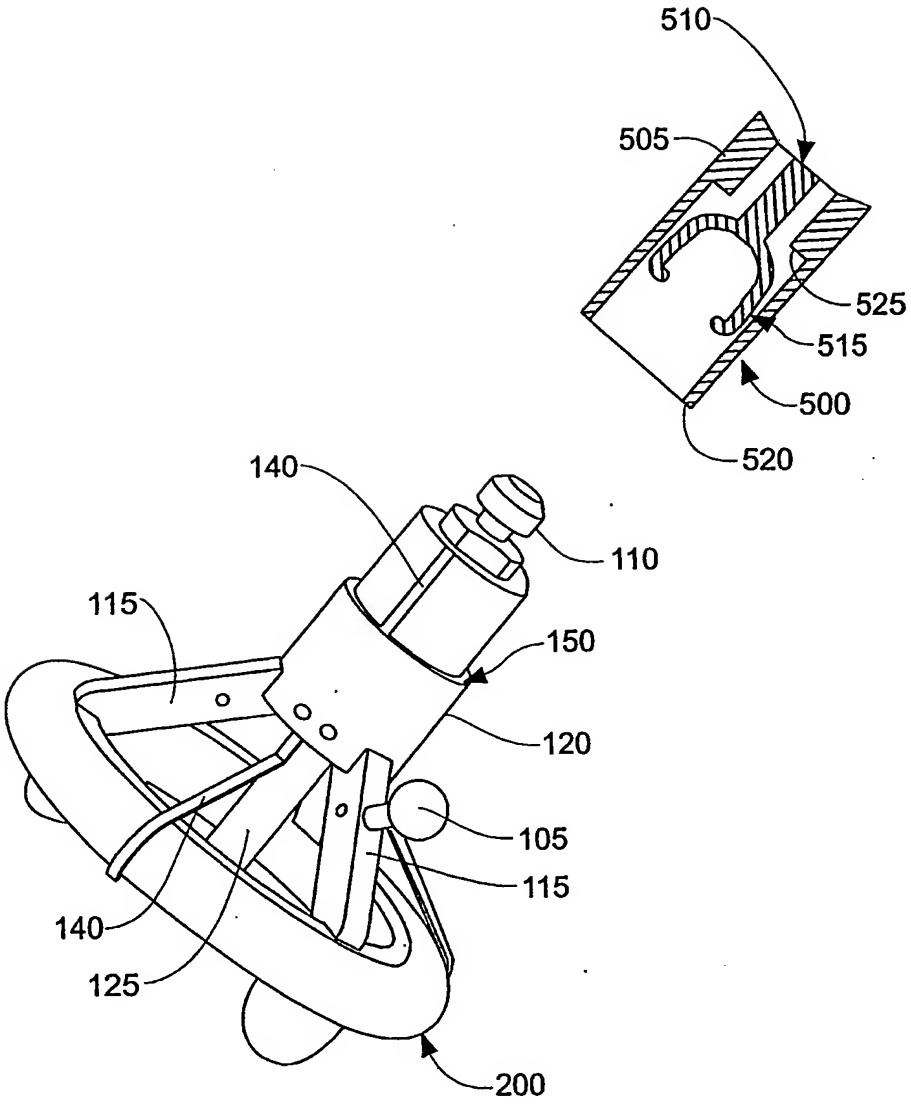

FIG. 8

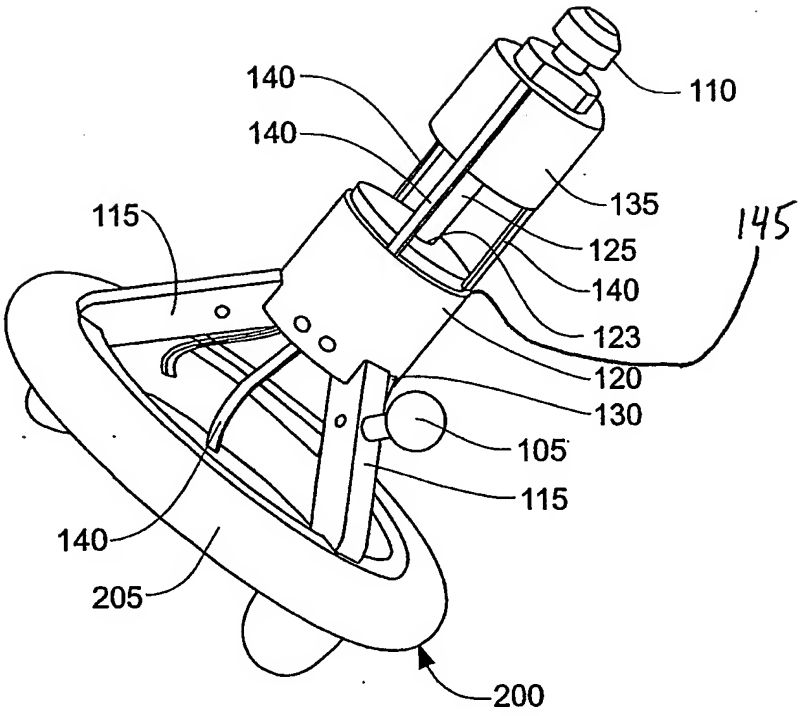

FIG. 9

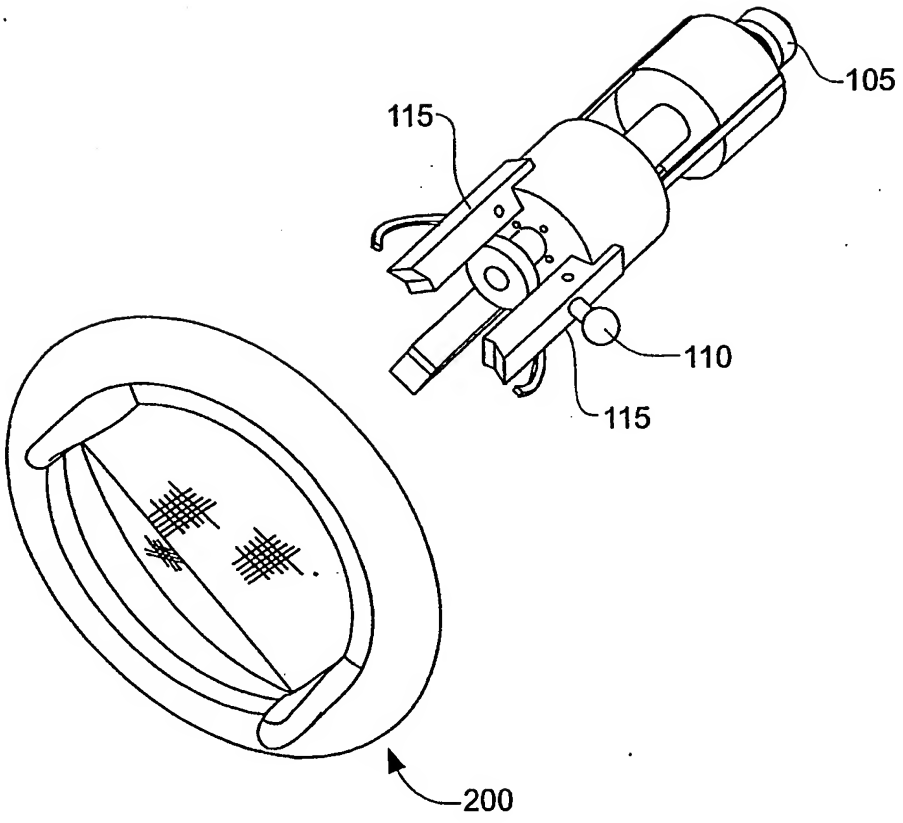

FIG. 10

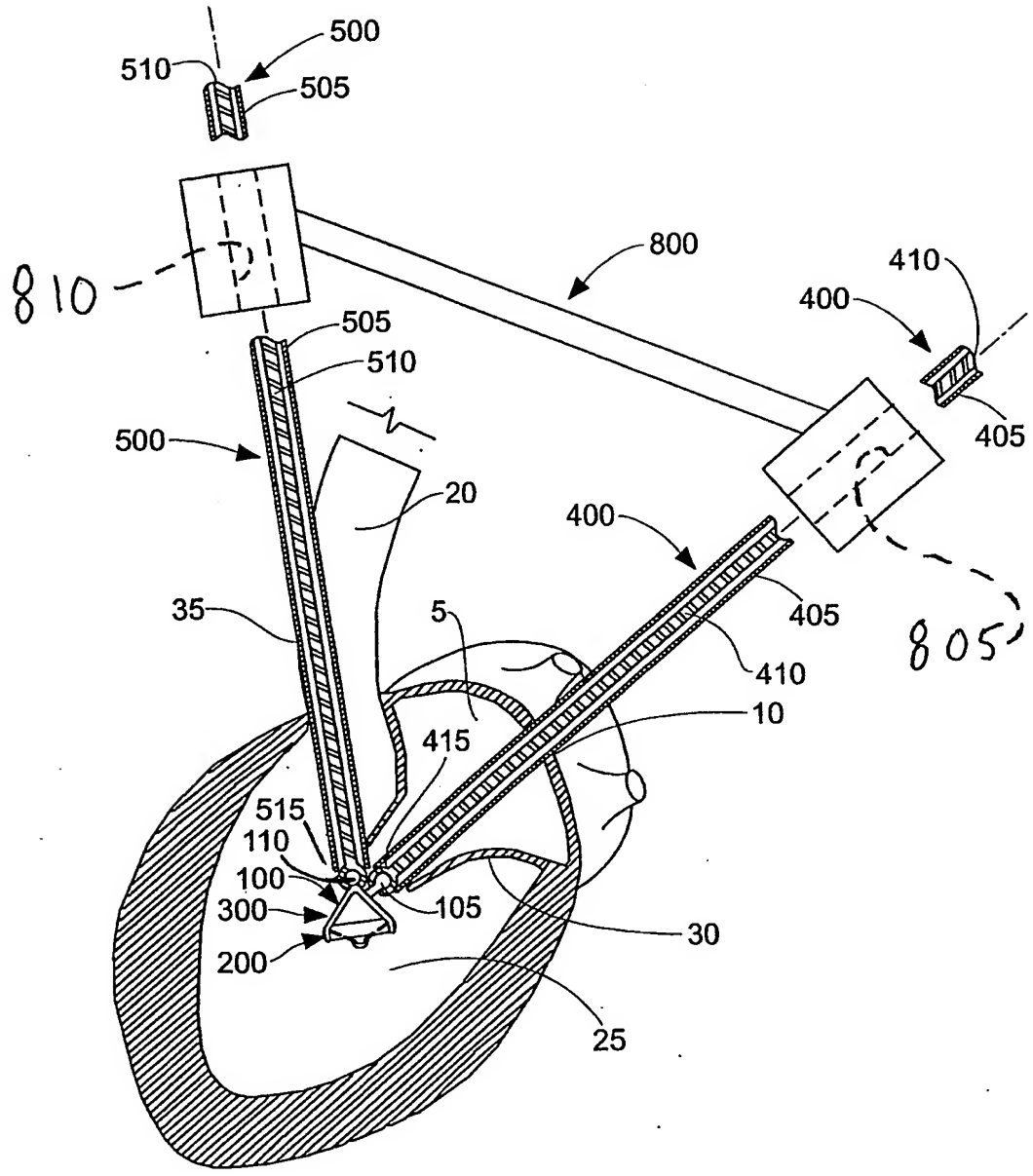
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FIG. 11

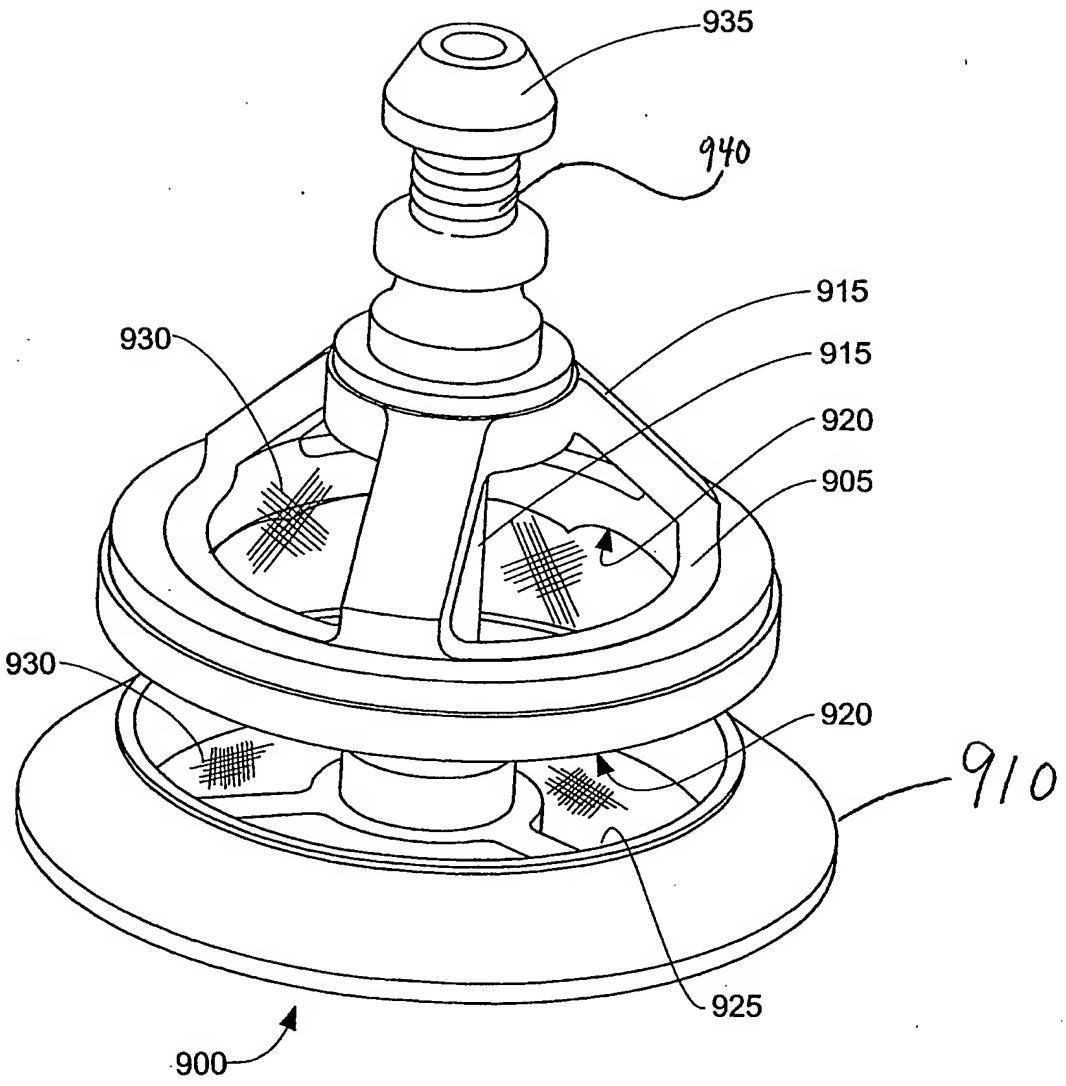

FIG. 12

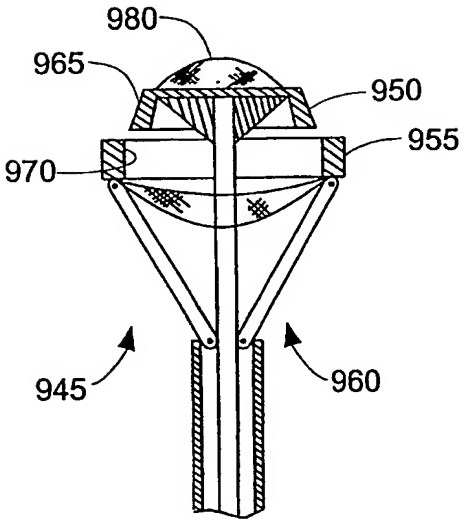

FIG. 14

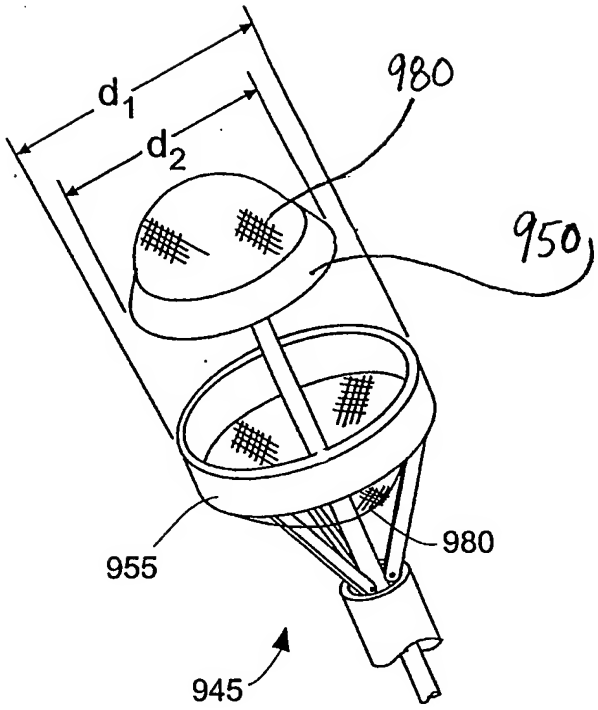

FIG. 15

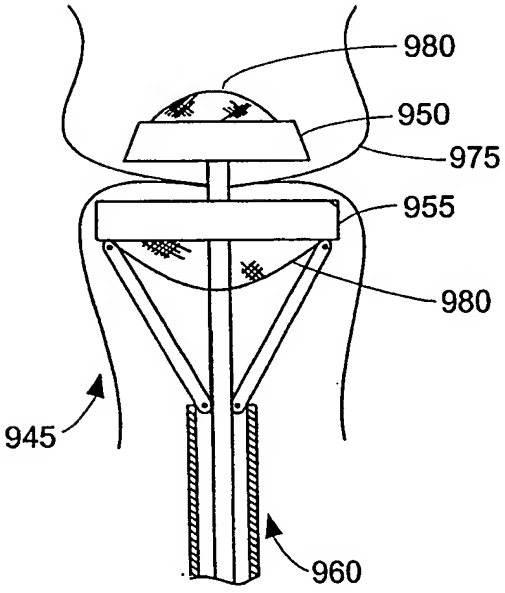

FIG. 13

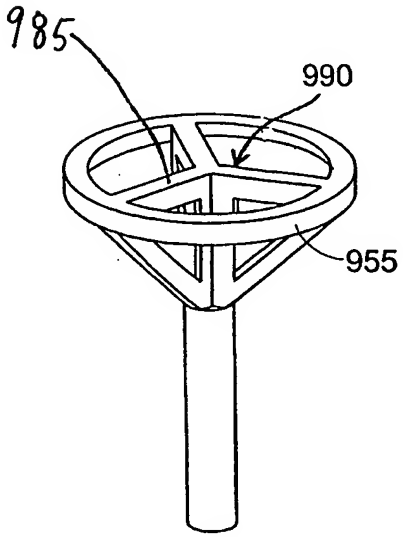

FIG. 16

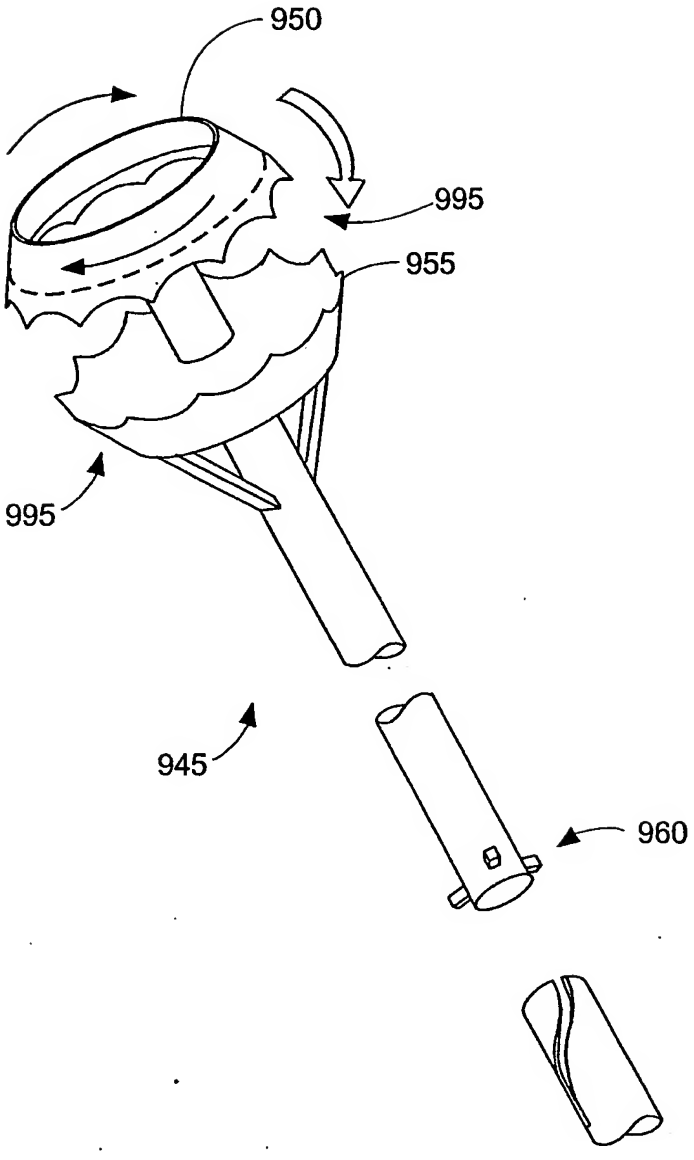

FIG. 17

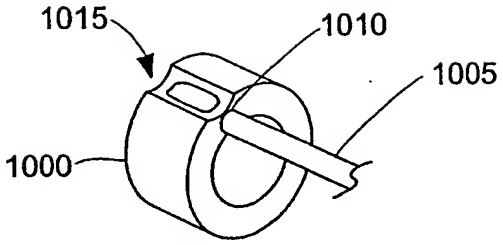

FIG. 18

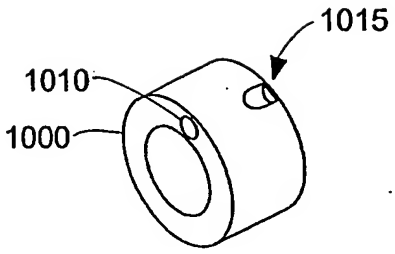

FIG. 19

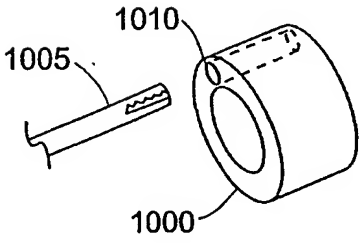

FIG. 20

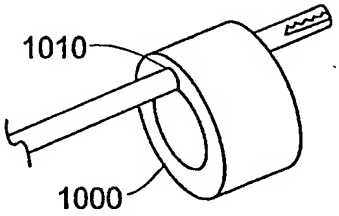

FIG. 21

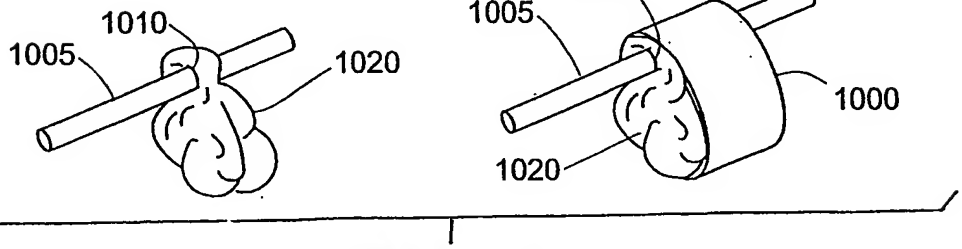

FIG. 22

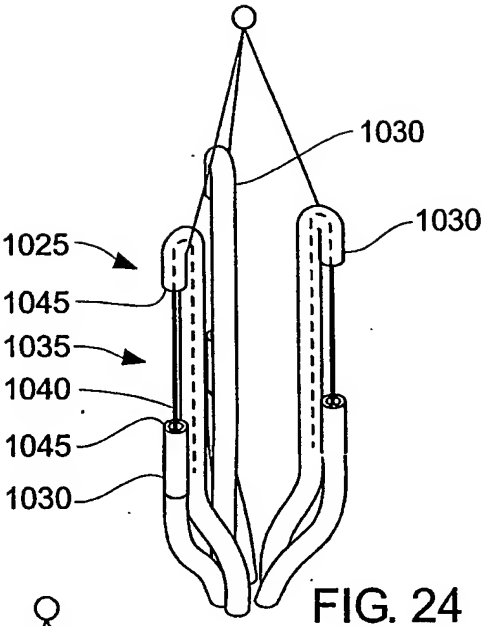

FIG. 24

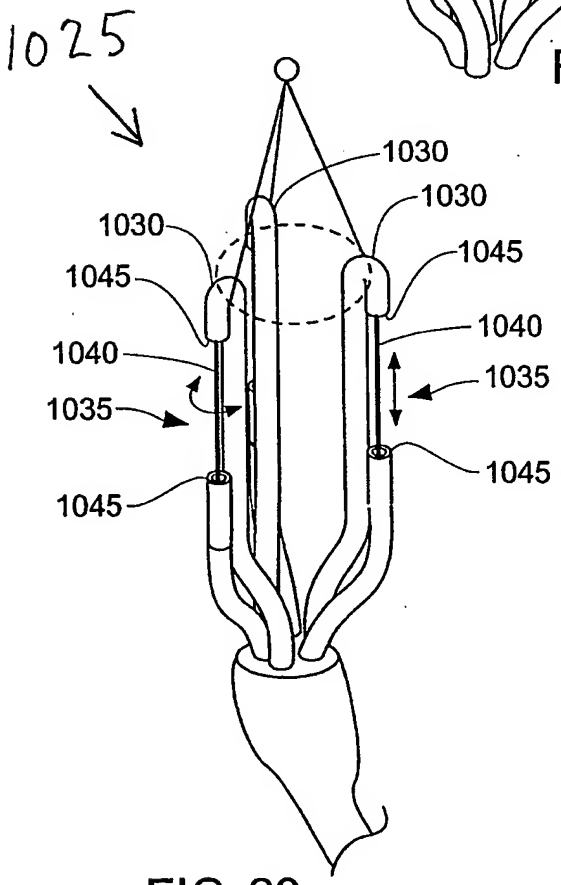

FIG. 23

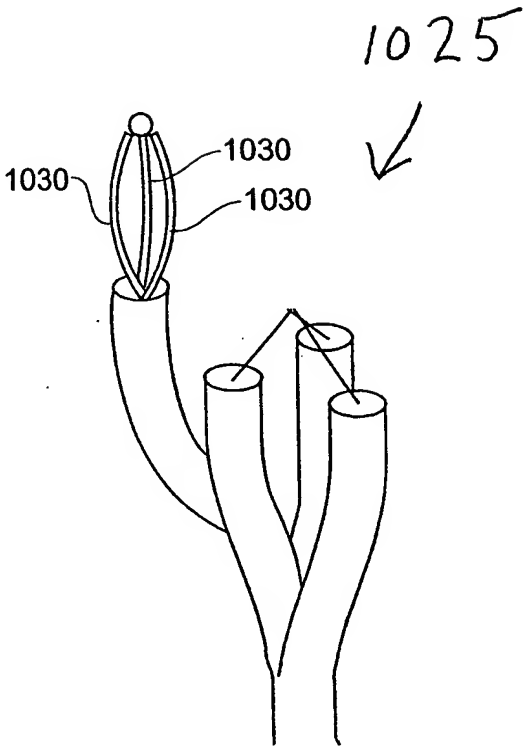

FIG. 25

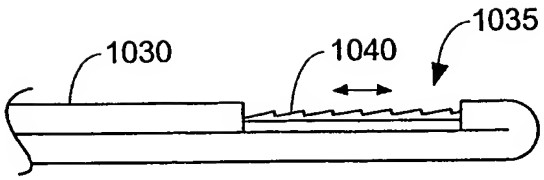

FIG. 26

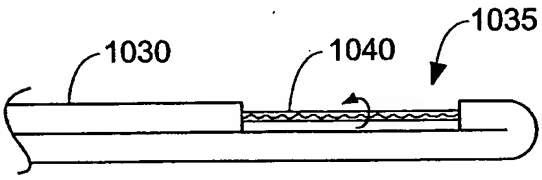

FIG. 27

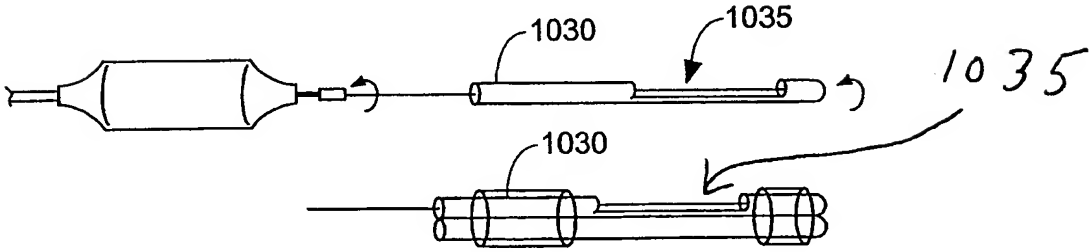

FIG. 28

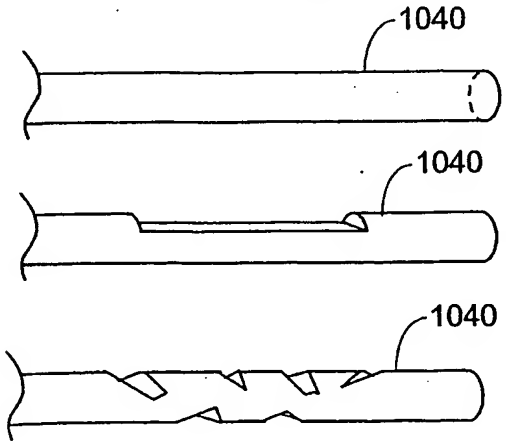

FIG. 29

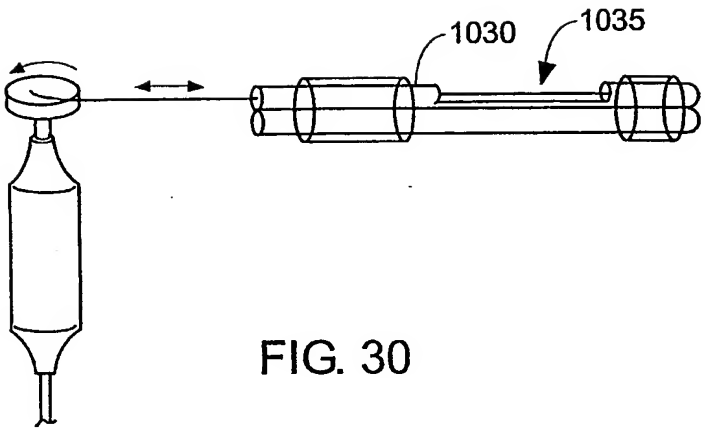

FIG. 30

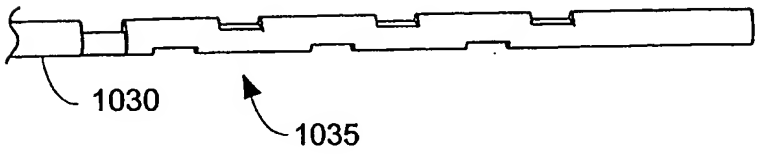

FIG. 31

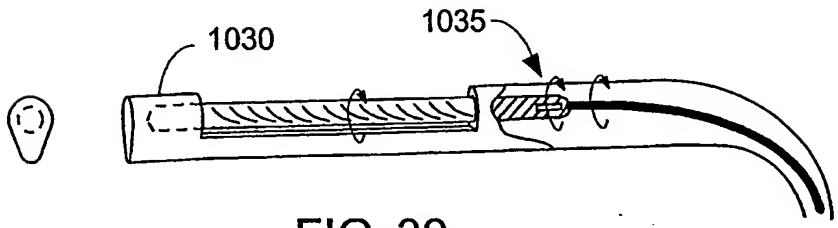

FIG. 32

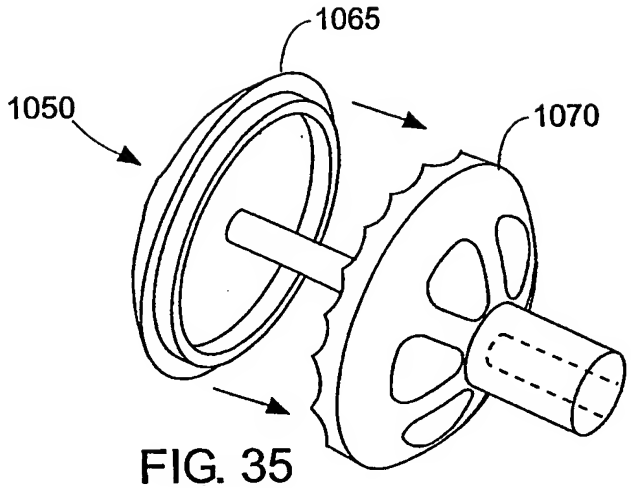

FIG. 35

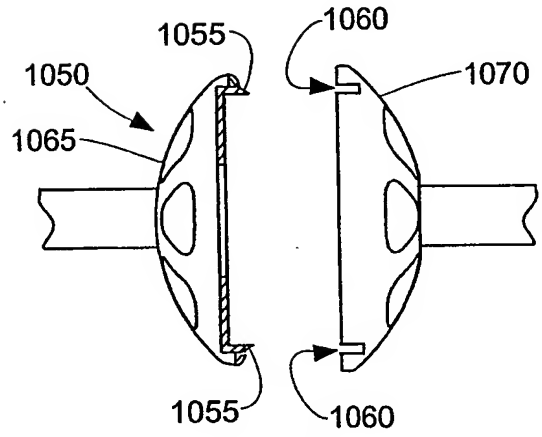

FIG. 34

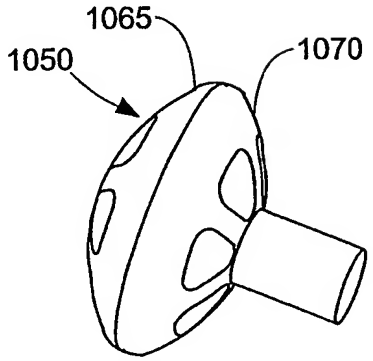

FIG. 33

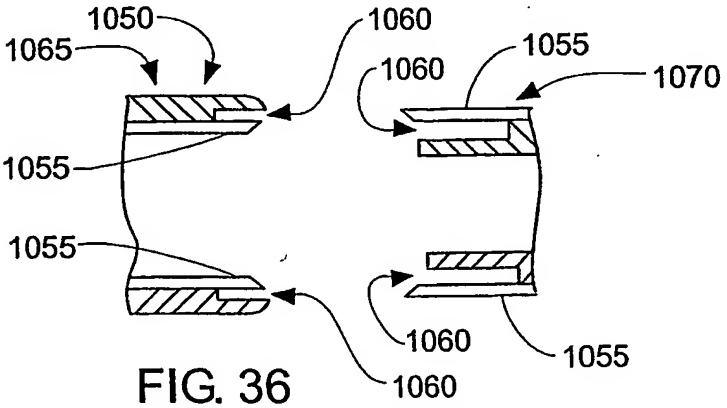

FIG. 36

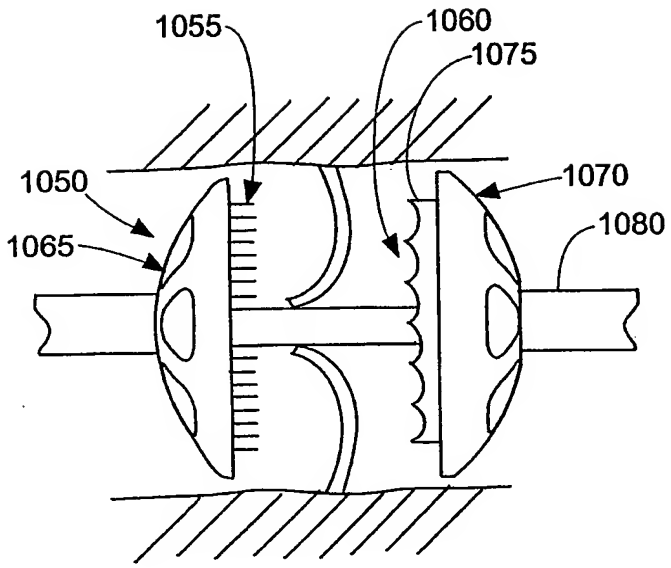

FIG. 37

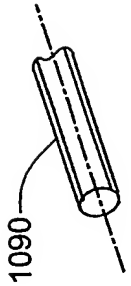

FIG. 38

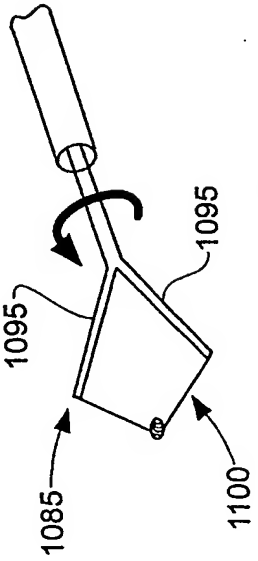

FIG. 39

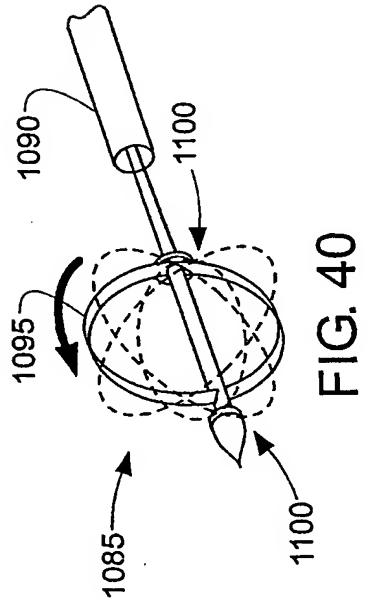

FIG. 40

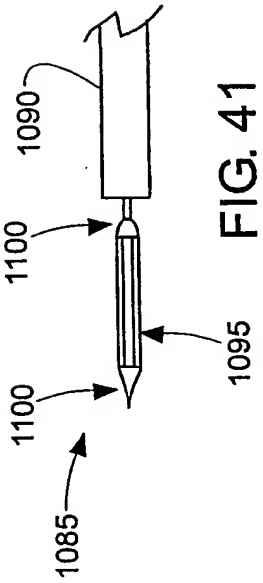

FIG. 41

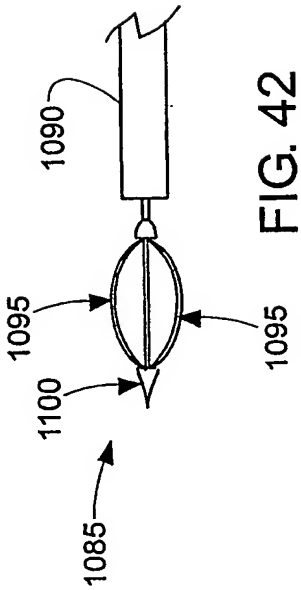

FIG. 42

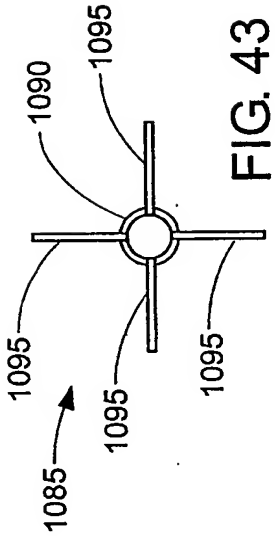

FIG. 43

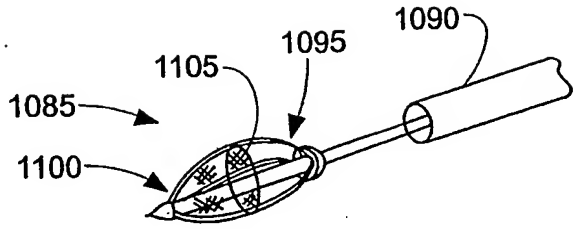

FIG. 44

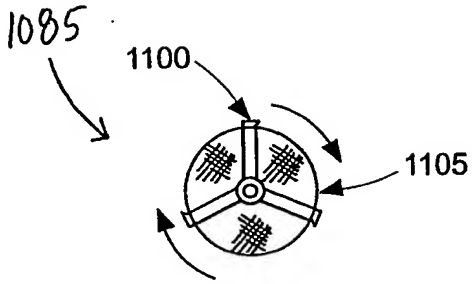

FIG. 46

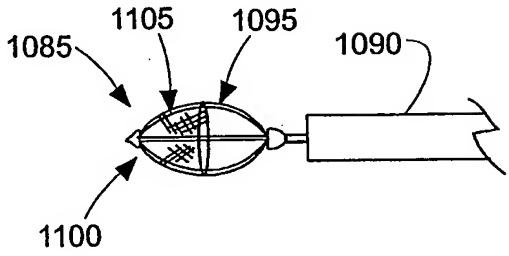

FIG. 45

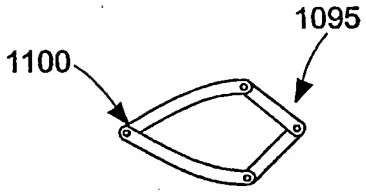

FIG. 47

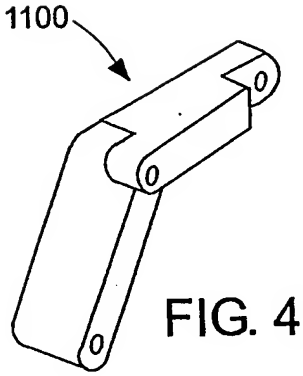

FIG. 48

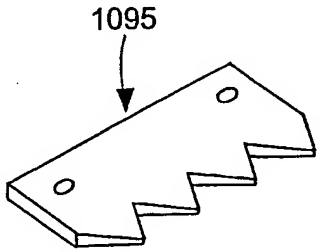

FIG. 49

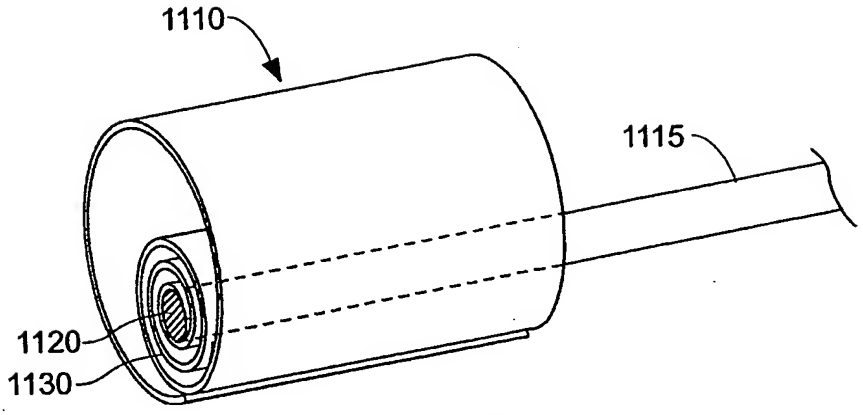

FIG. 50

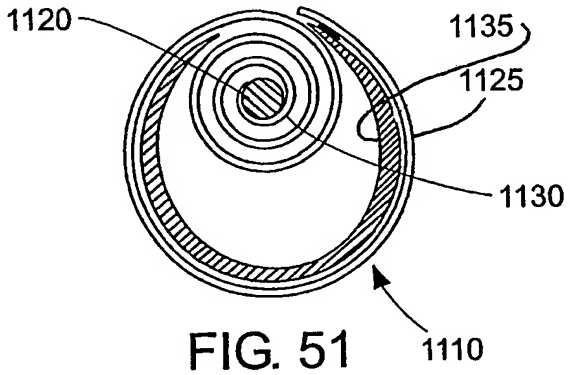

FIG. 51

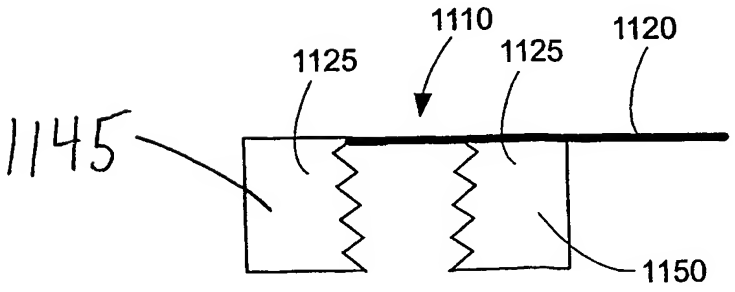

FIG. 53

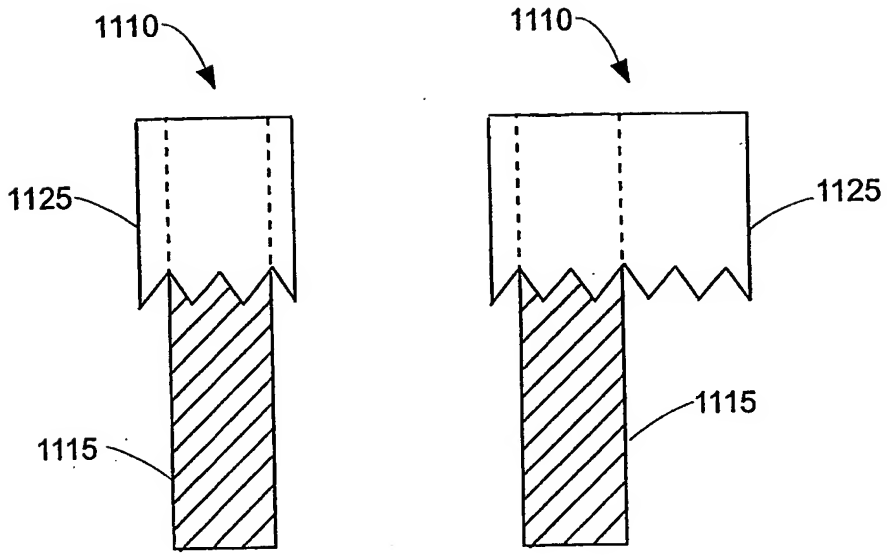

FIG. 54

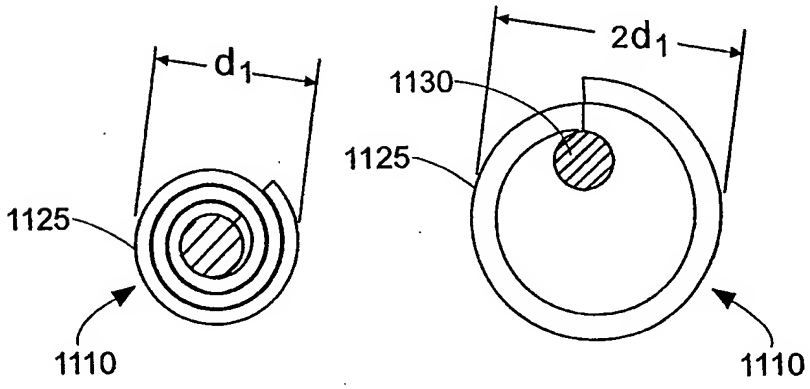

FIG. 52

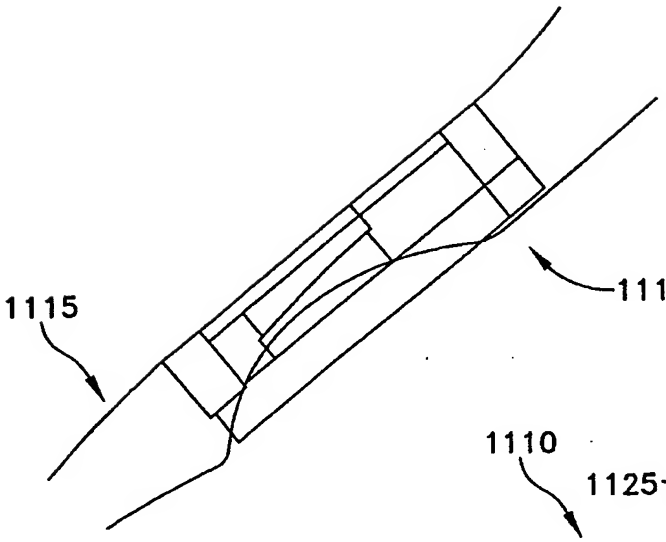

FIG. 57

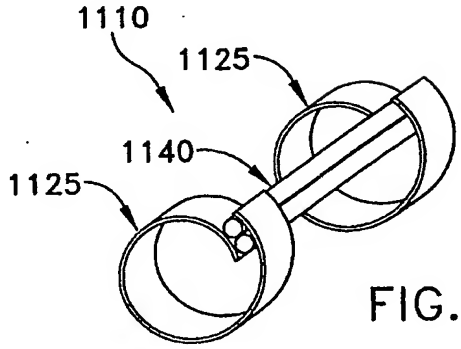

FIG. 56

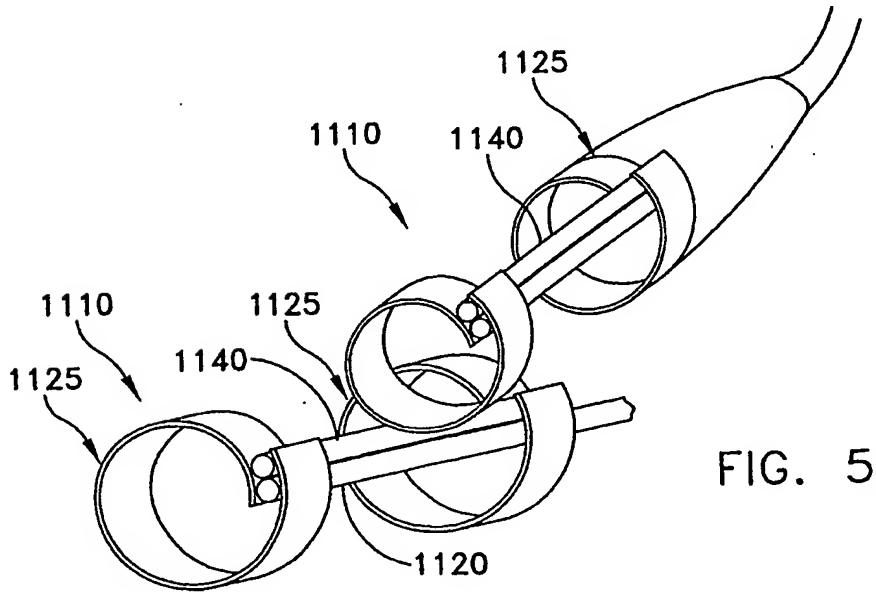

FIG. 55

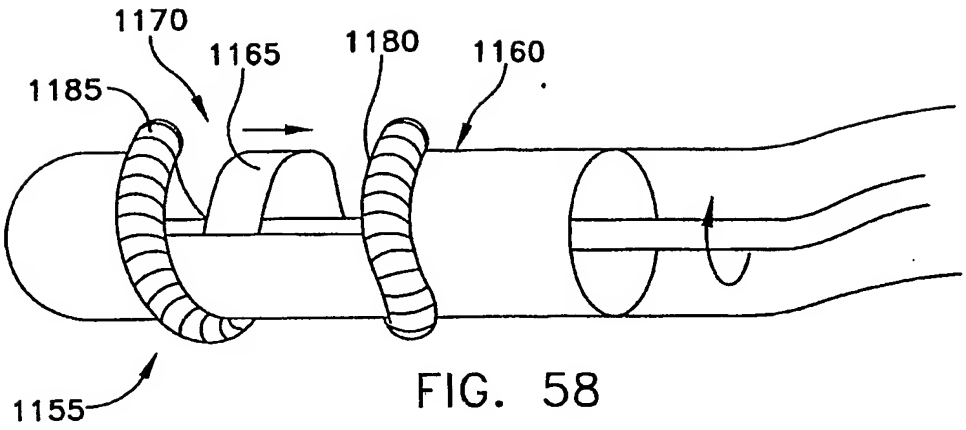

FIG. 58

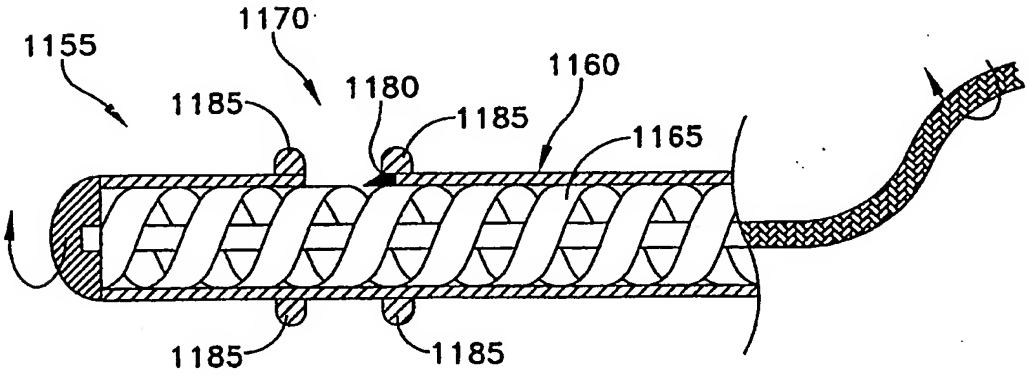

FIG. 59

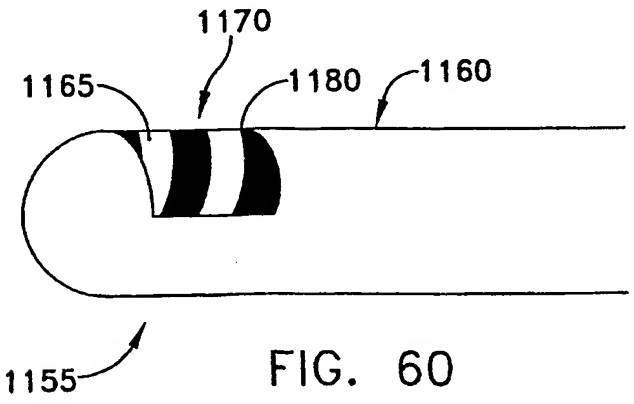

FIG. 60

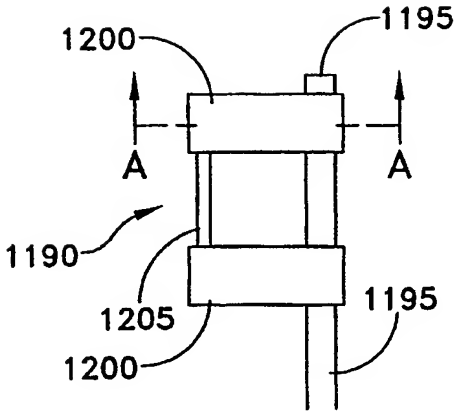

FIG. 62

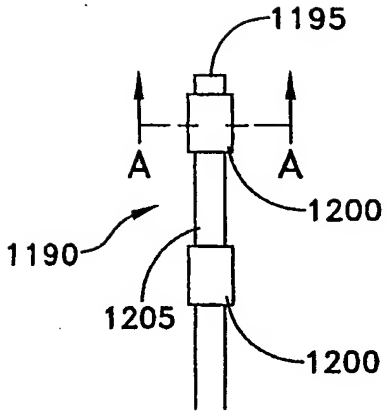

FIG. 63

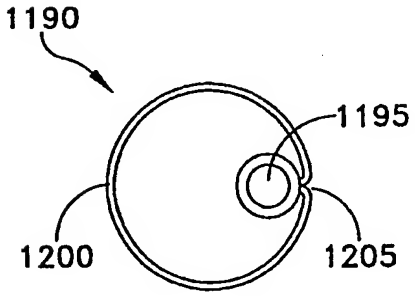

FIG. 62 A–A

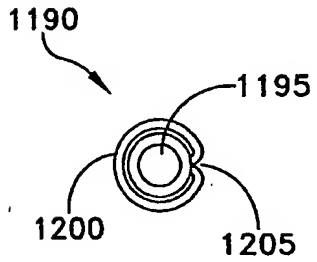

FIG. 63 A–A

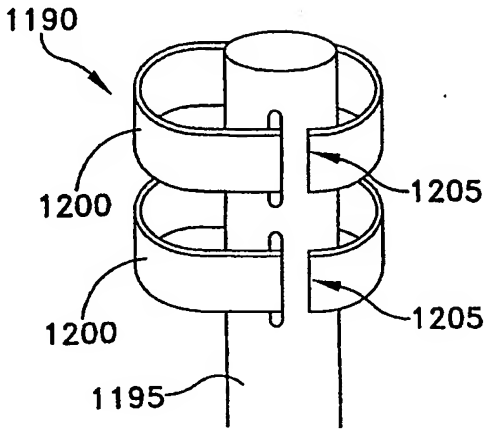

FIG. 61

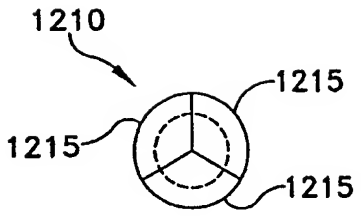

FIG. 65

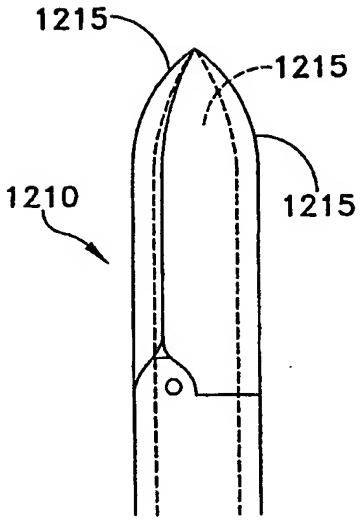

FIG. 64

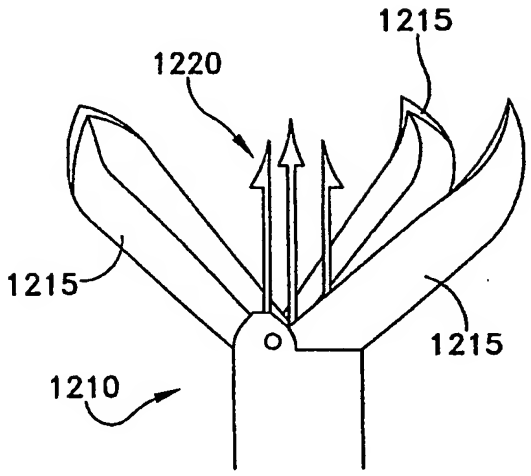

FIG. 66

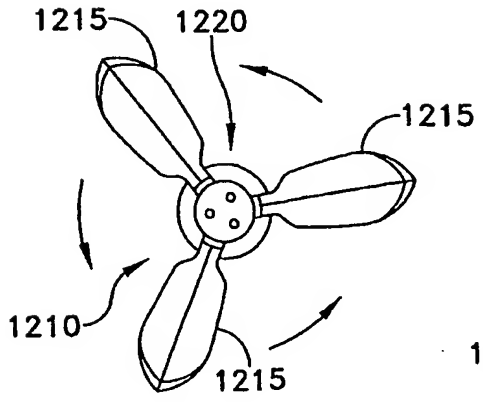

FIG. 67

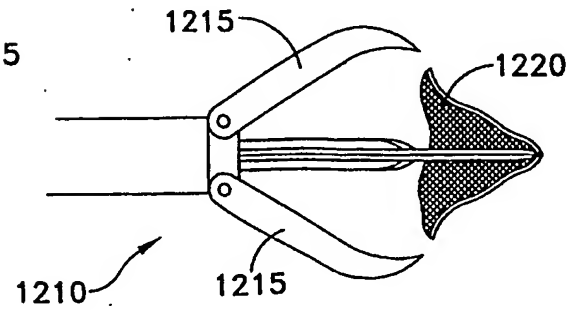

FIG. 68

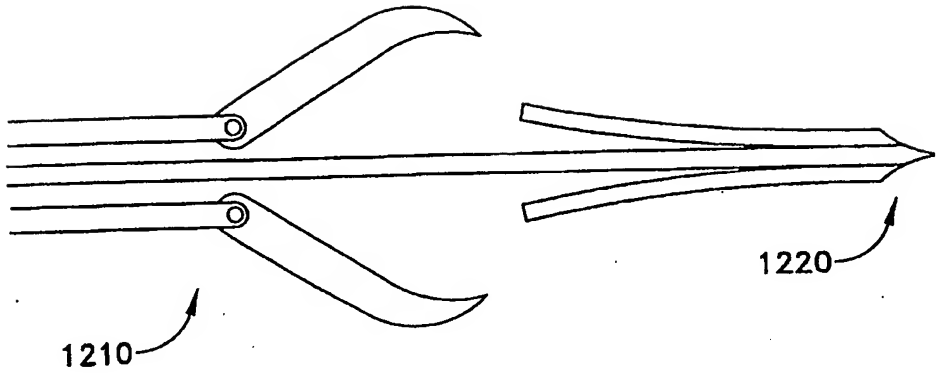

FIG. 69

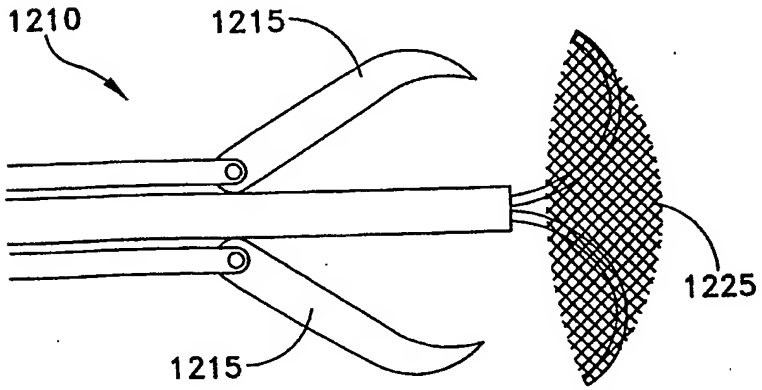

FIG. 70

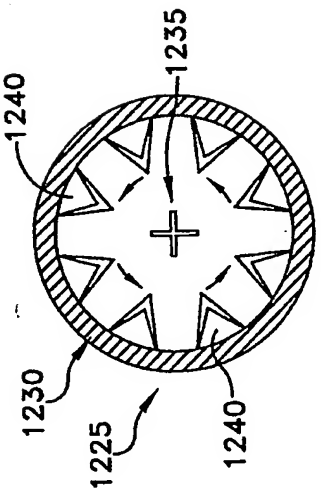

FIG. 72

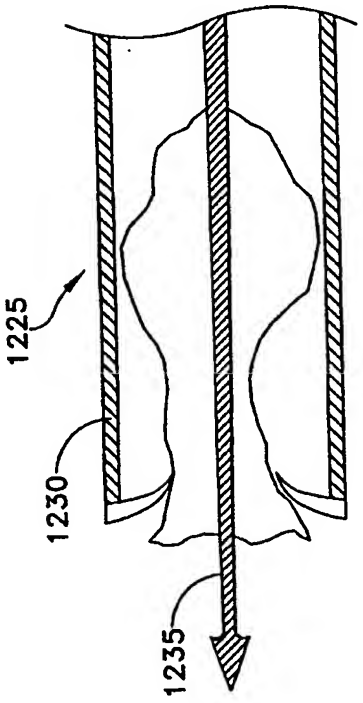

FIG. 71

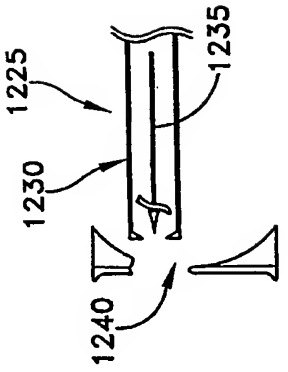

FIG. 76

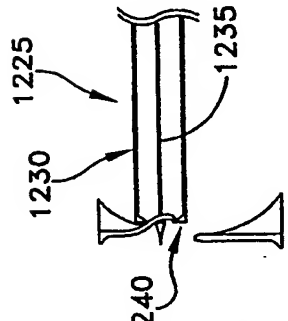

FIG. 75

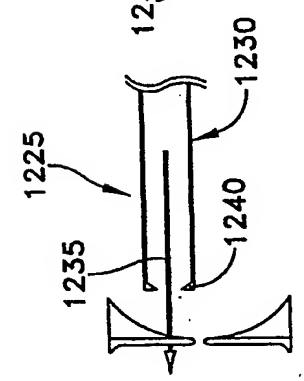

FIG. 74

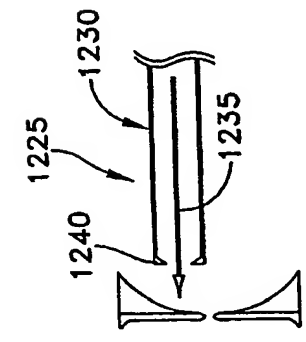

FIG. 73

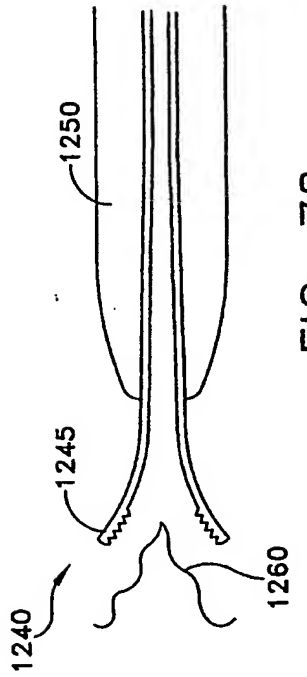

FIG. 78

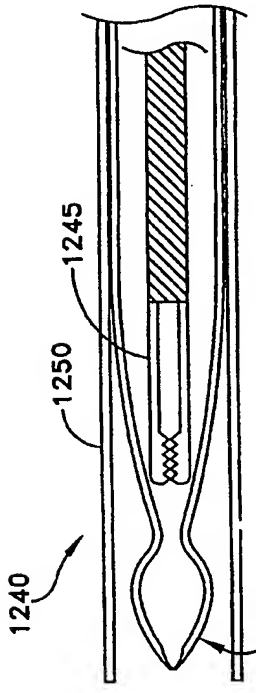

FIG. 77

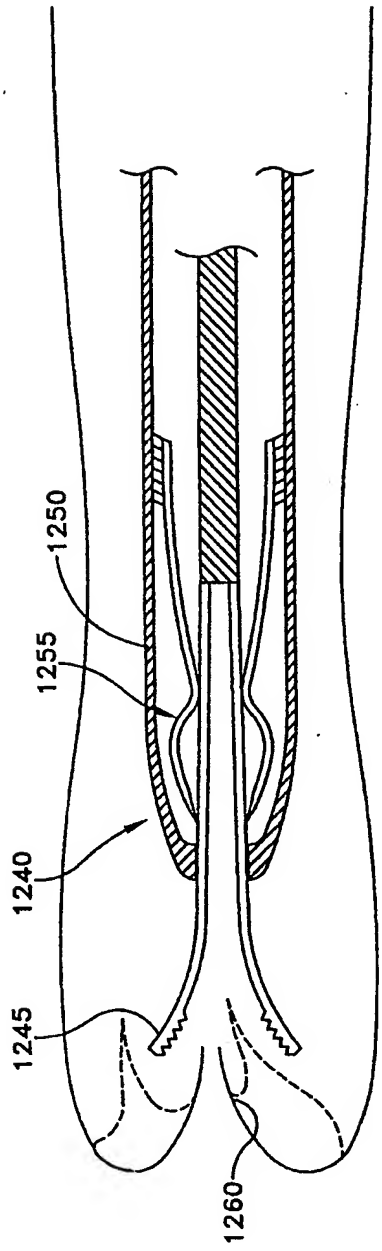

FIG. 79

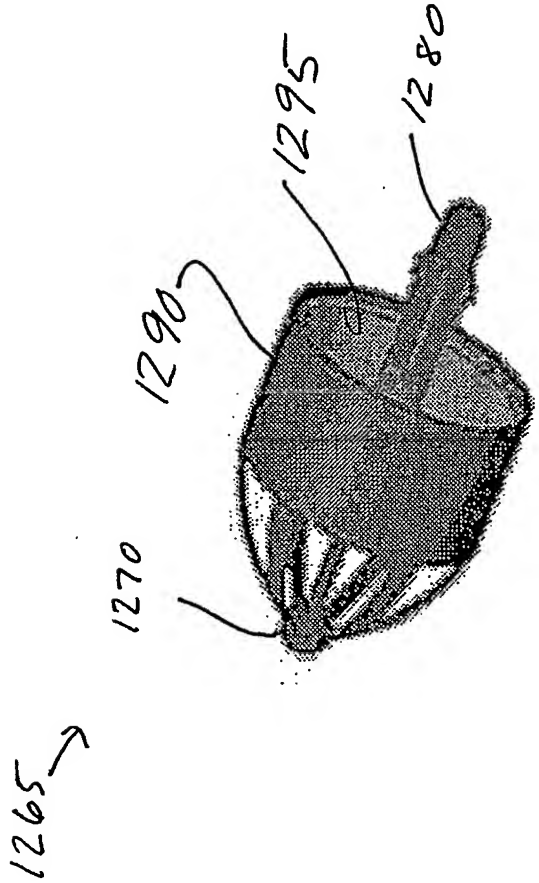

FIG. 80

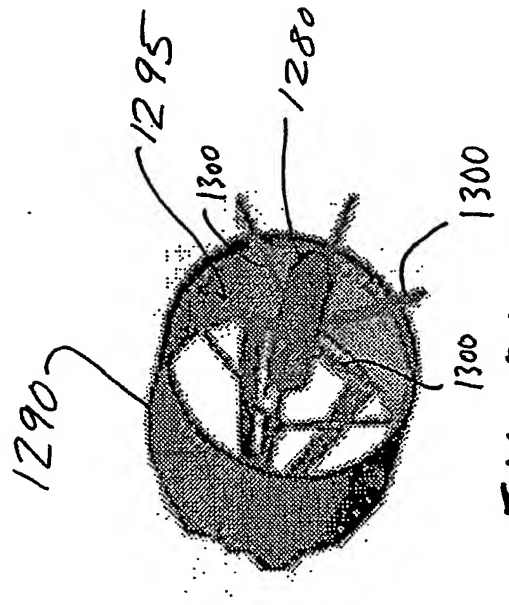

FIG. 81

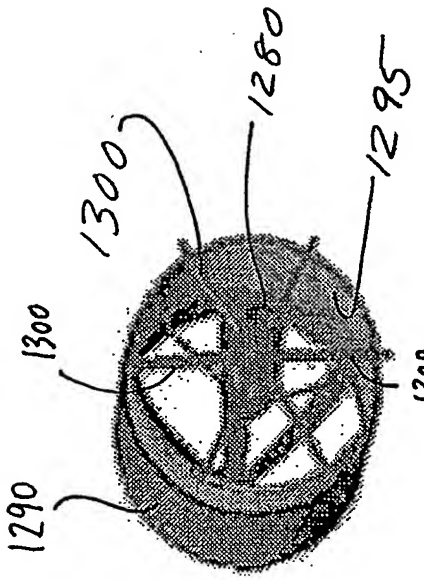

FIG. 82

1265

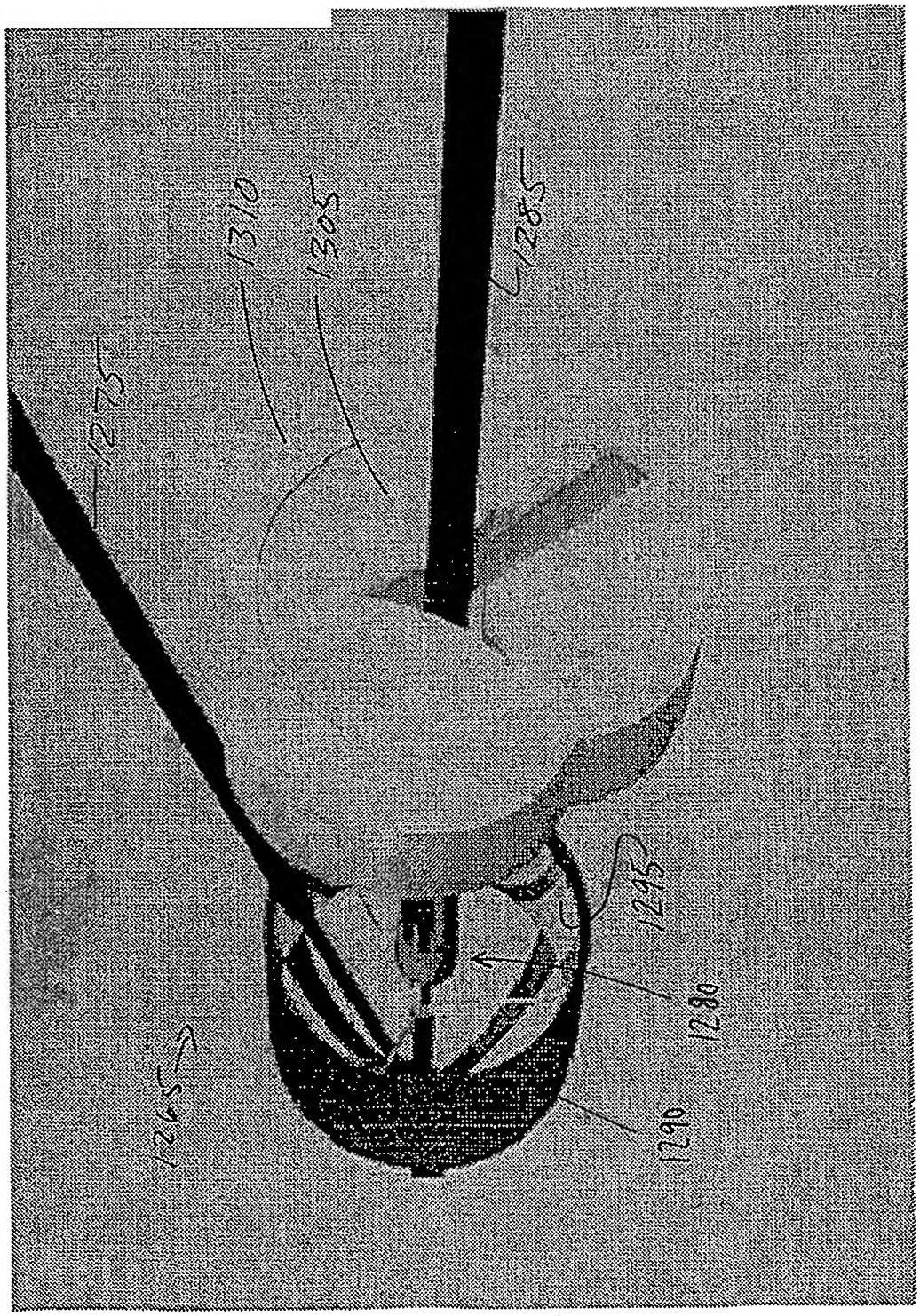

FIG. 83

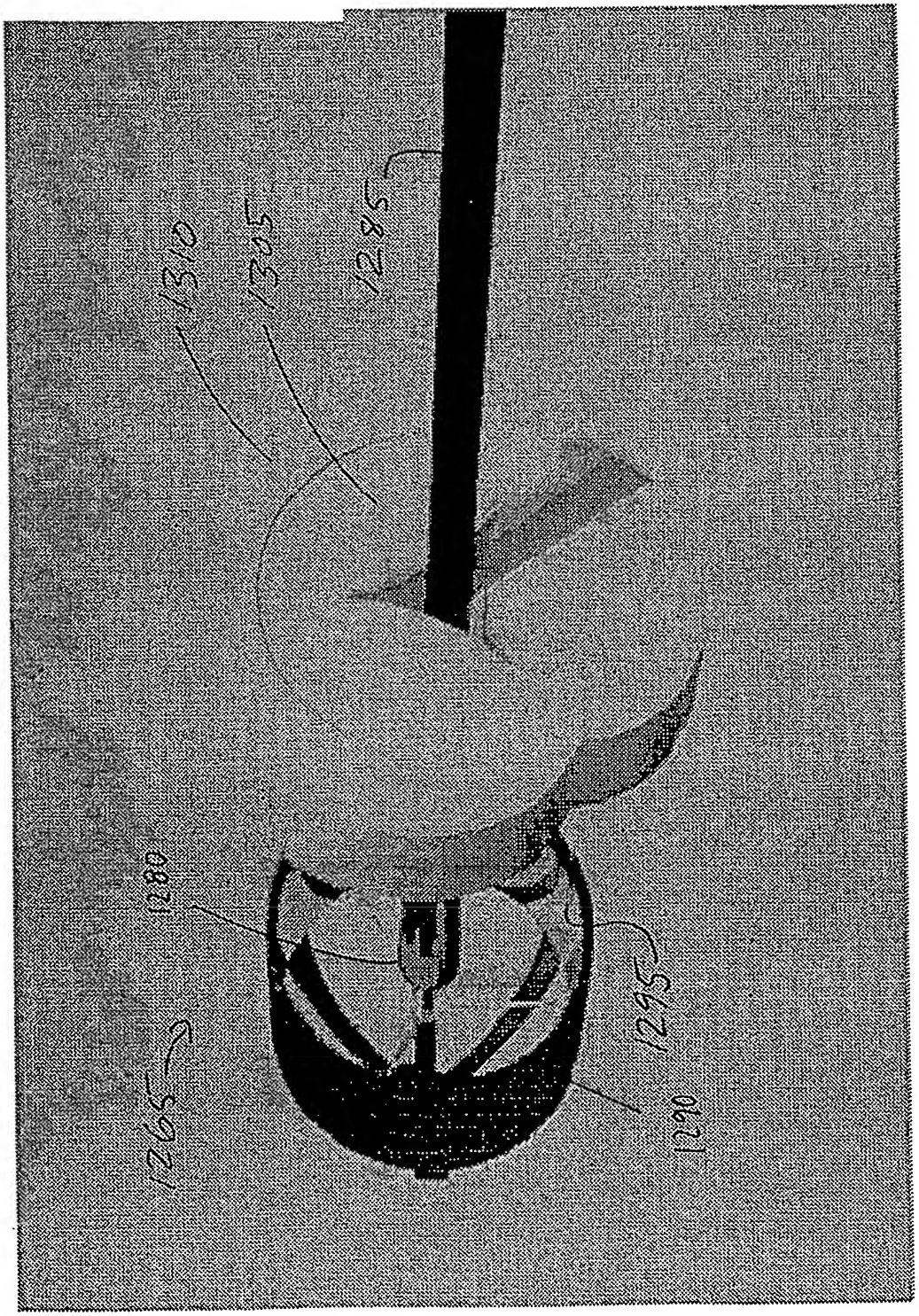

FIG. 84

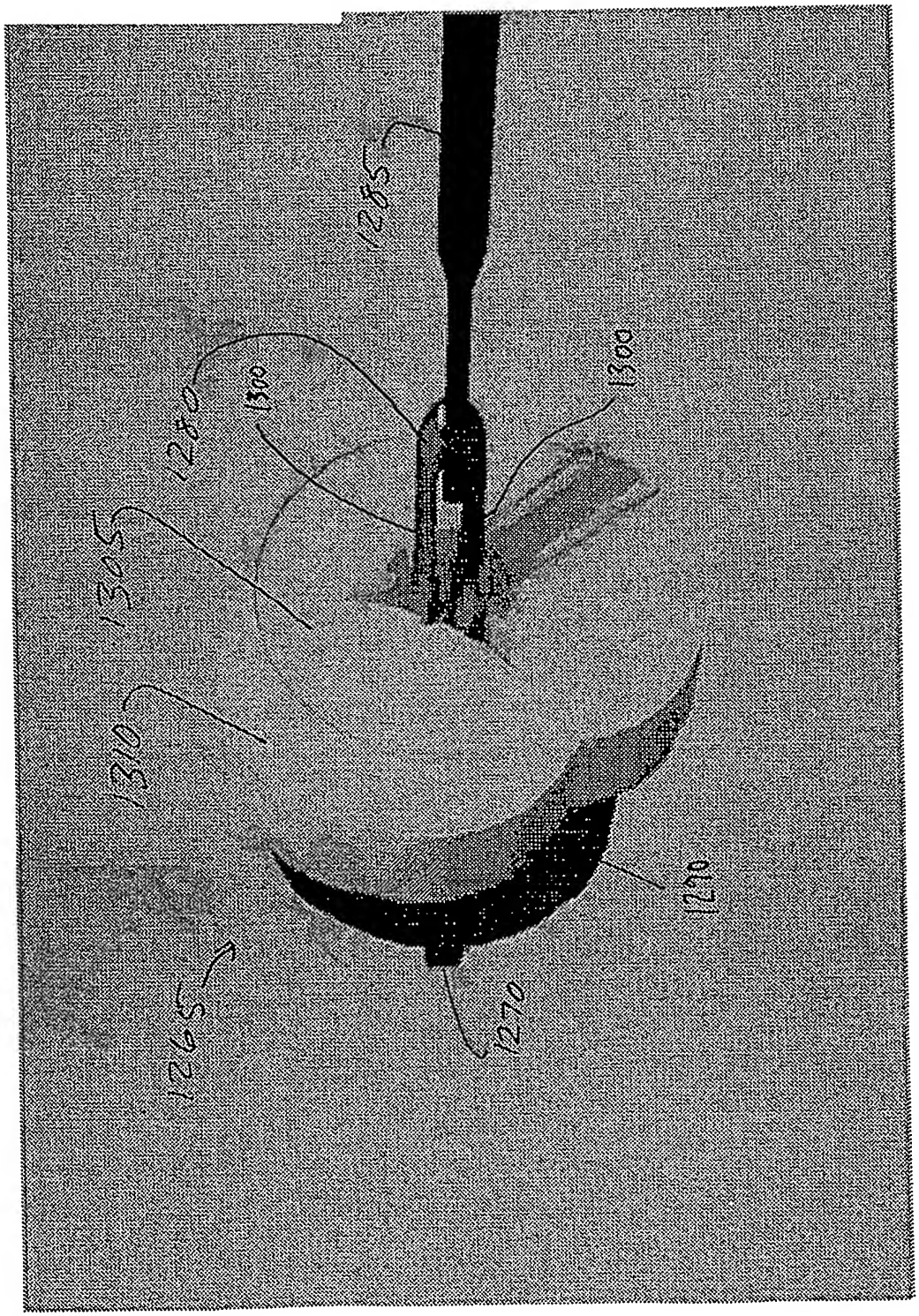

FIG. 85

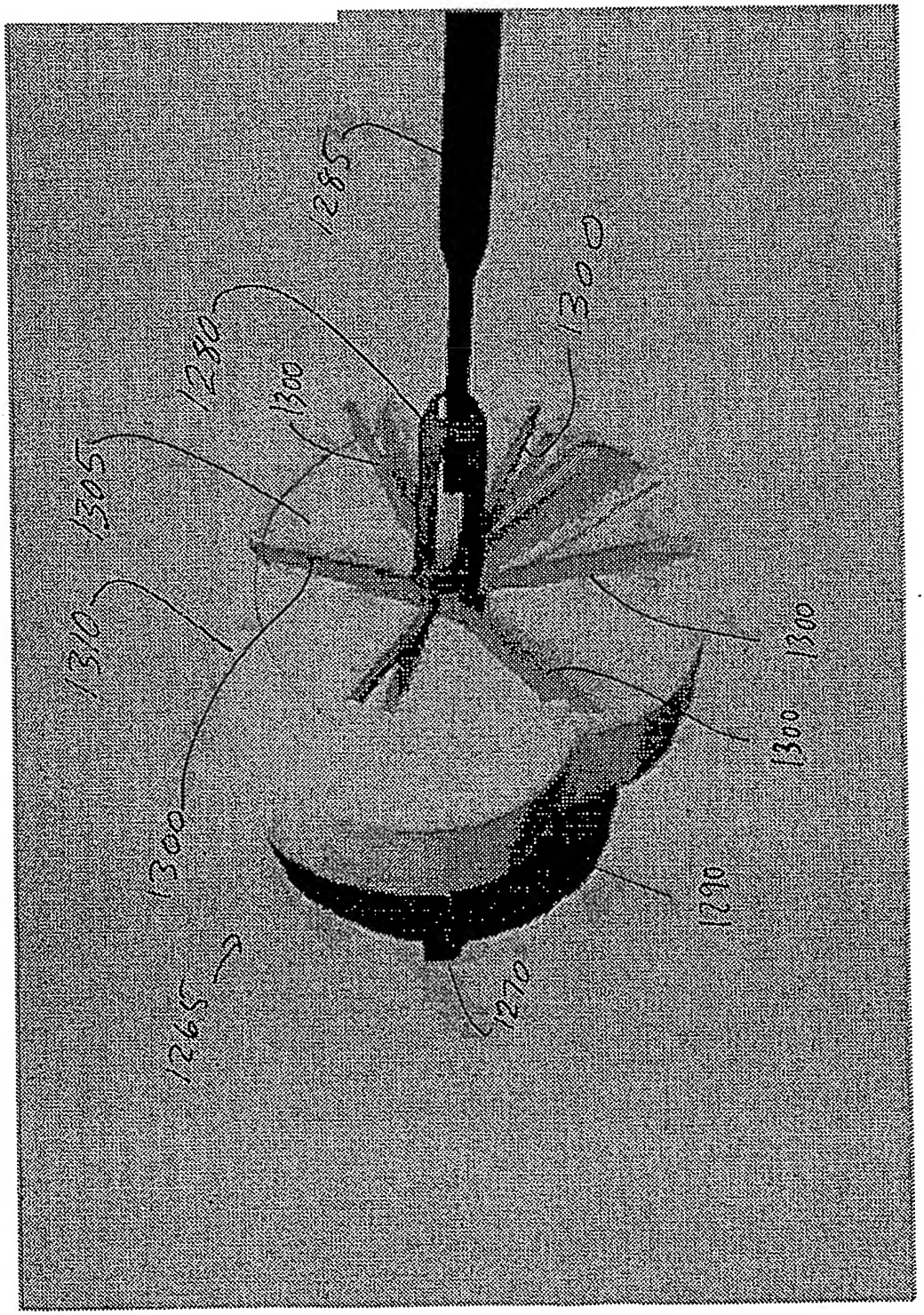
1255
1250
1300
1305
1310
1300
1245
1270
1290
1300
1300
1300
1300

Fig. 86

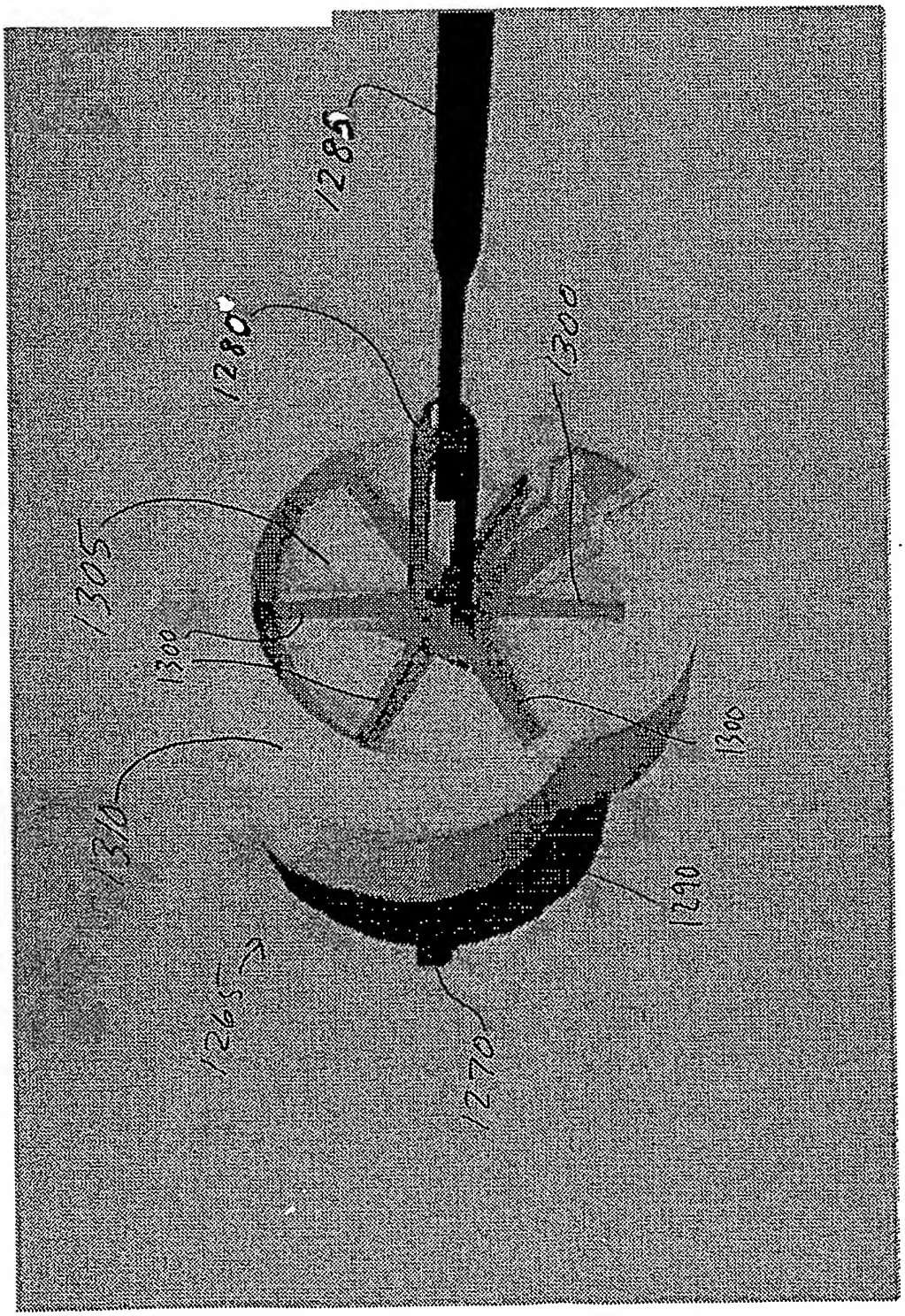

FIG. 87

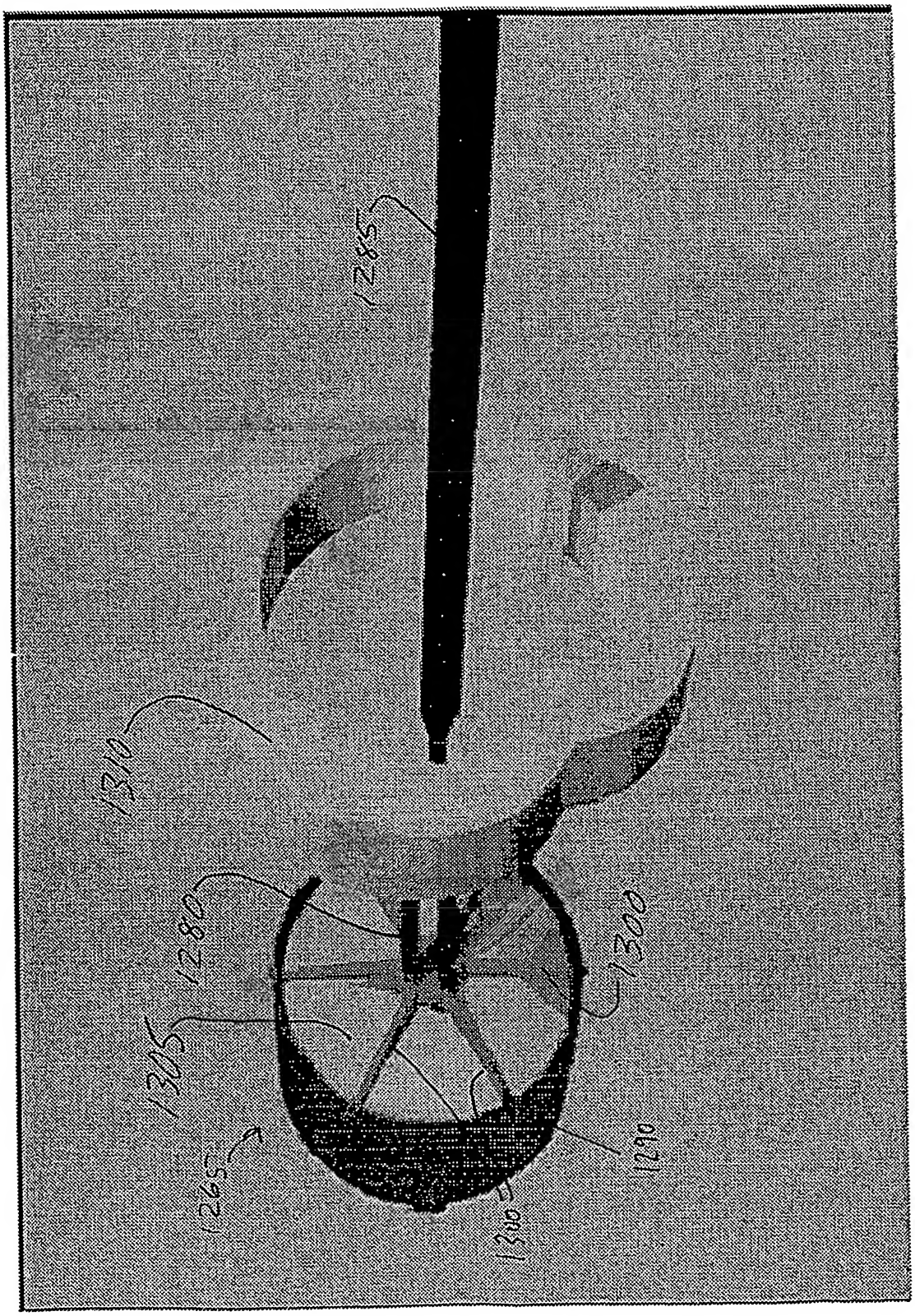

FIG. 88

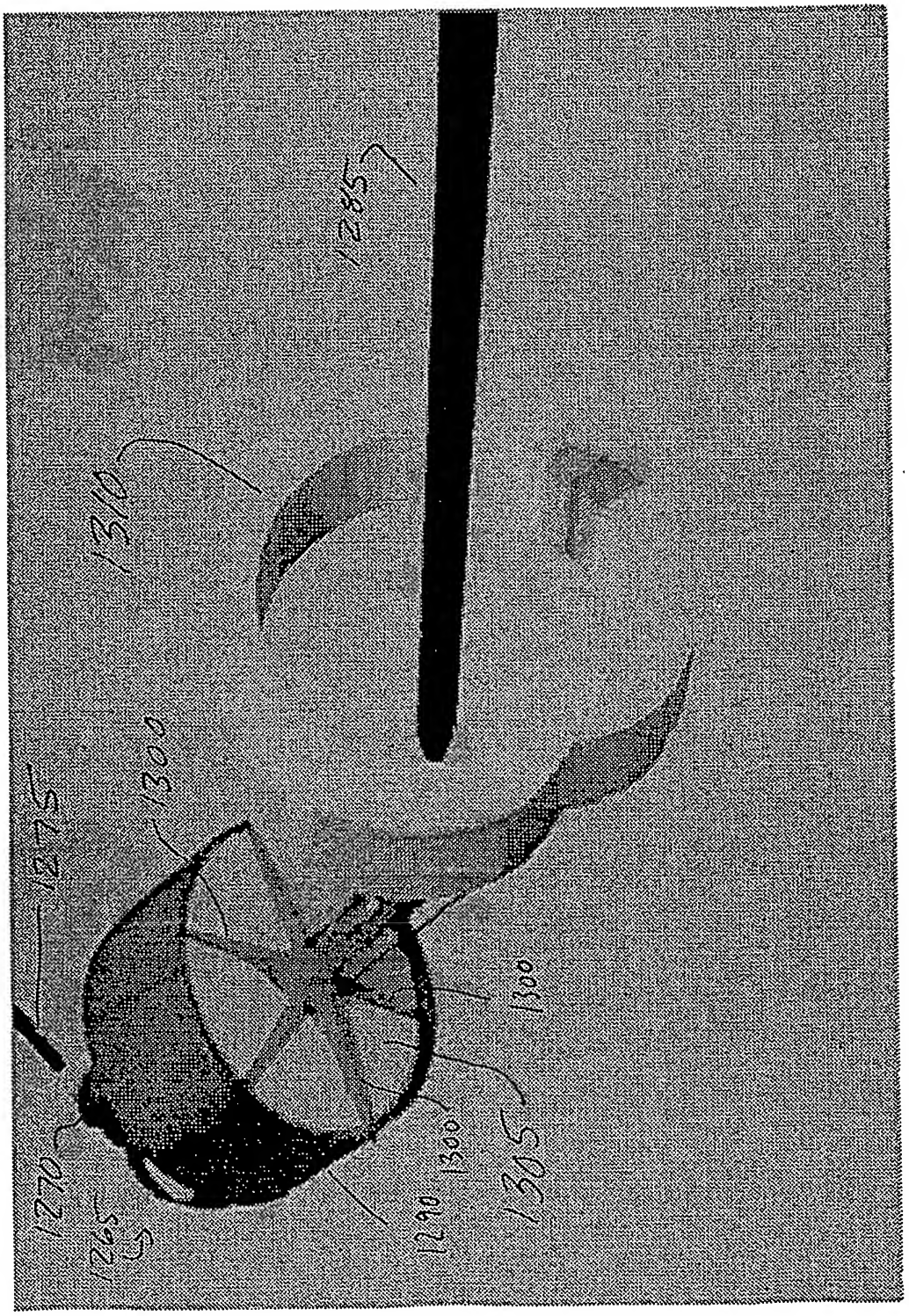

FIG. 89

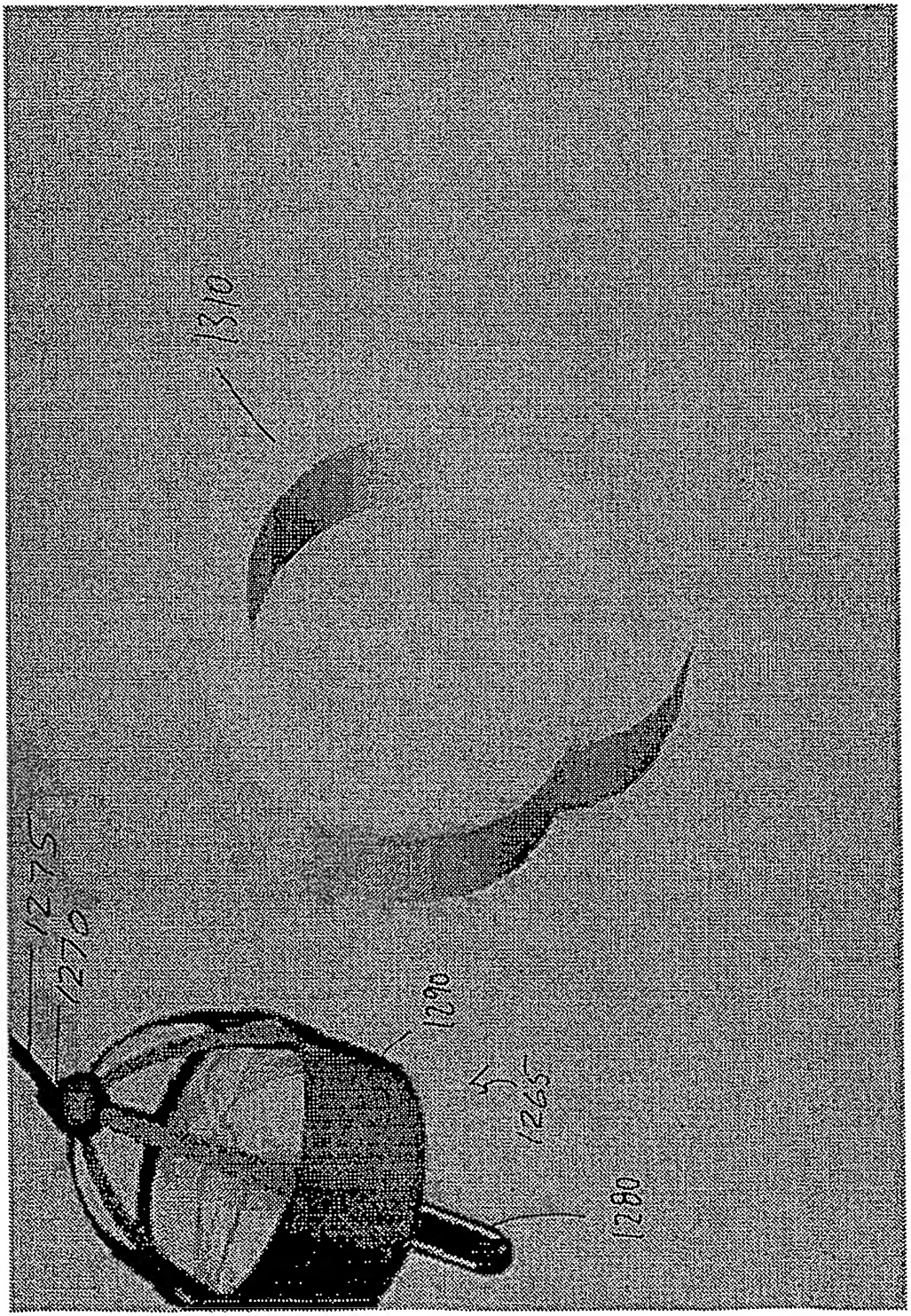

FIG. 90

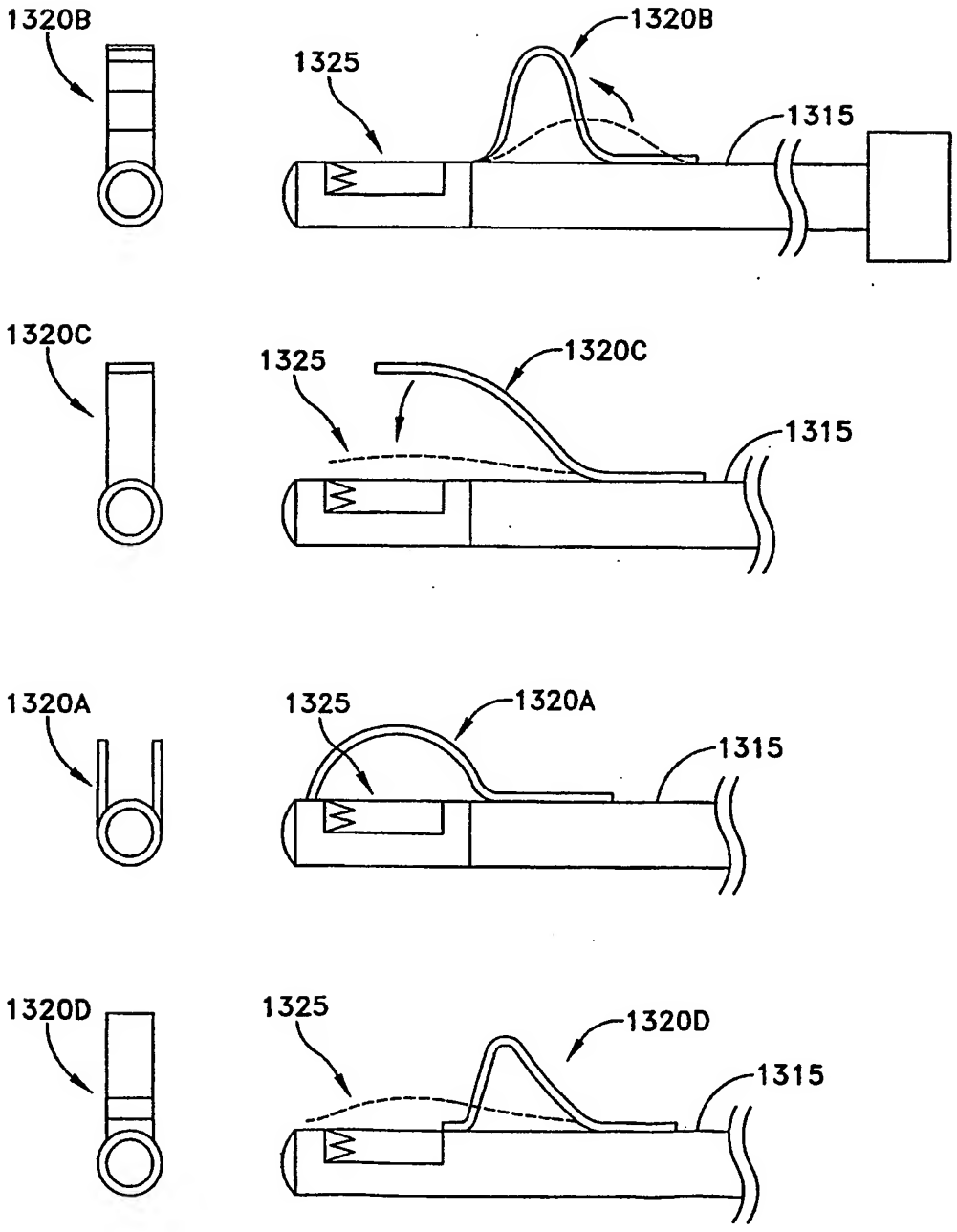
1320B
1325
1320B
1315
1320C
1325
1320C
1315
1320A
1325
1320A
1315
1320D
1325
1320D
1315

FIG. 91

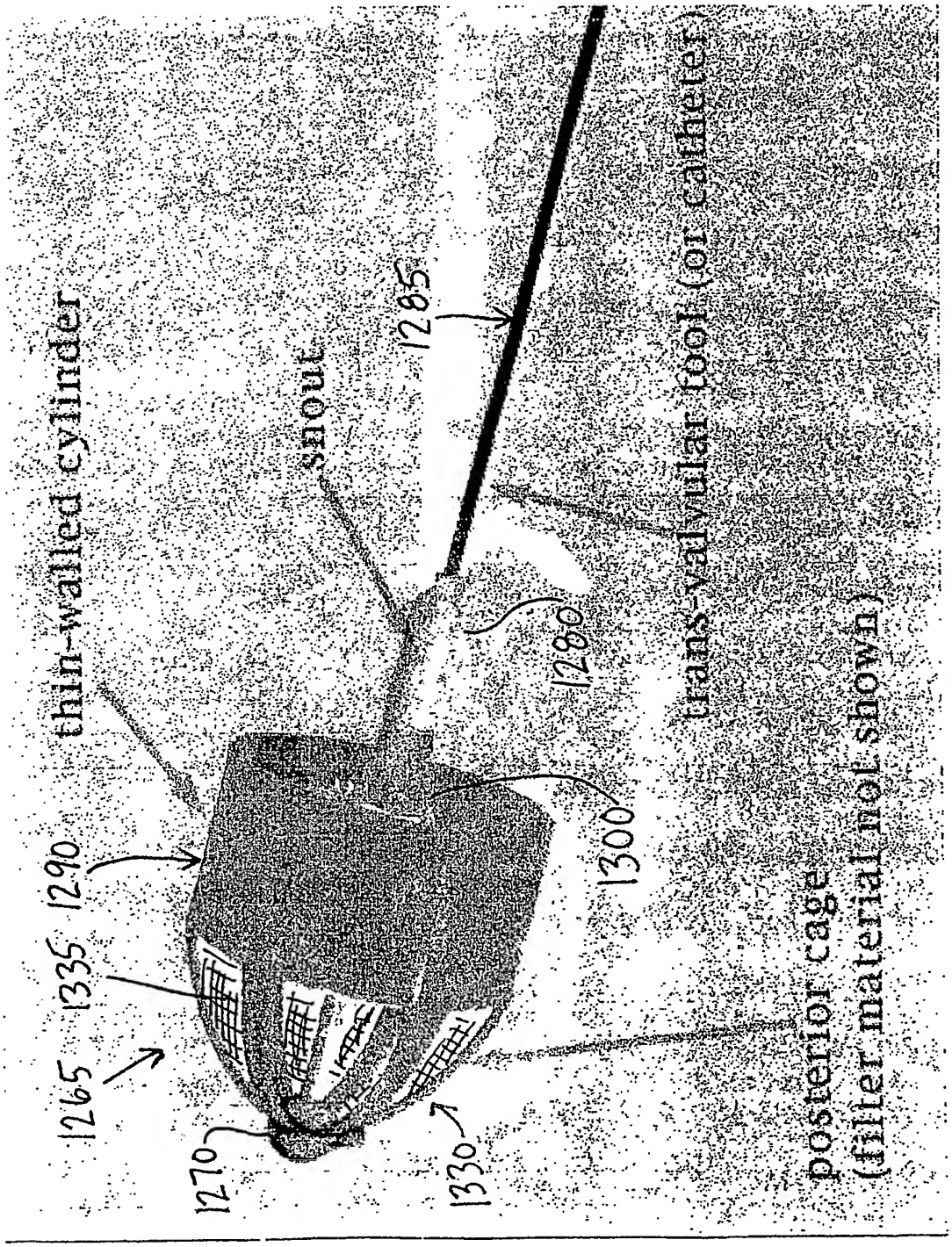
thin-walled cylinder
snout
trans-valvular tool (or catheter)
posterior cage
(filler material not shown)
1265
1270
1290
1335
1330
1280
1285
1300

FIG. 92

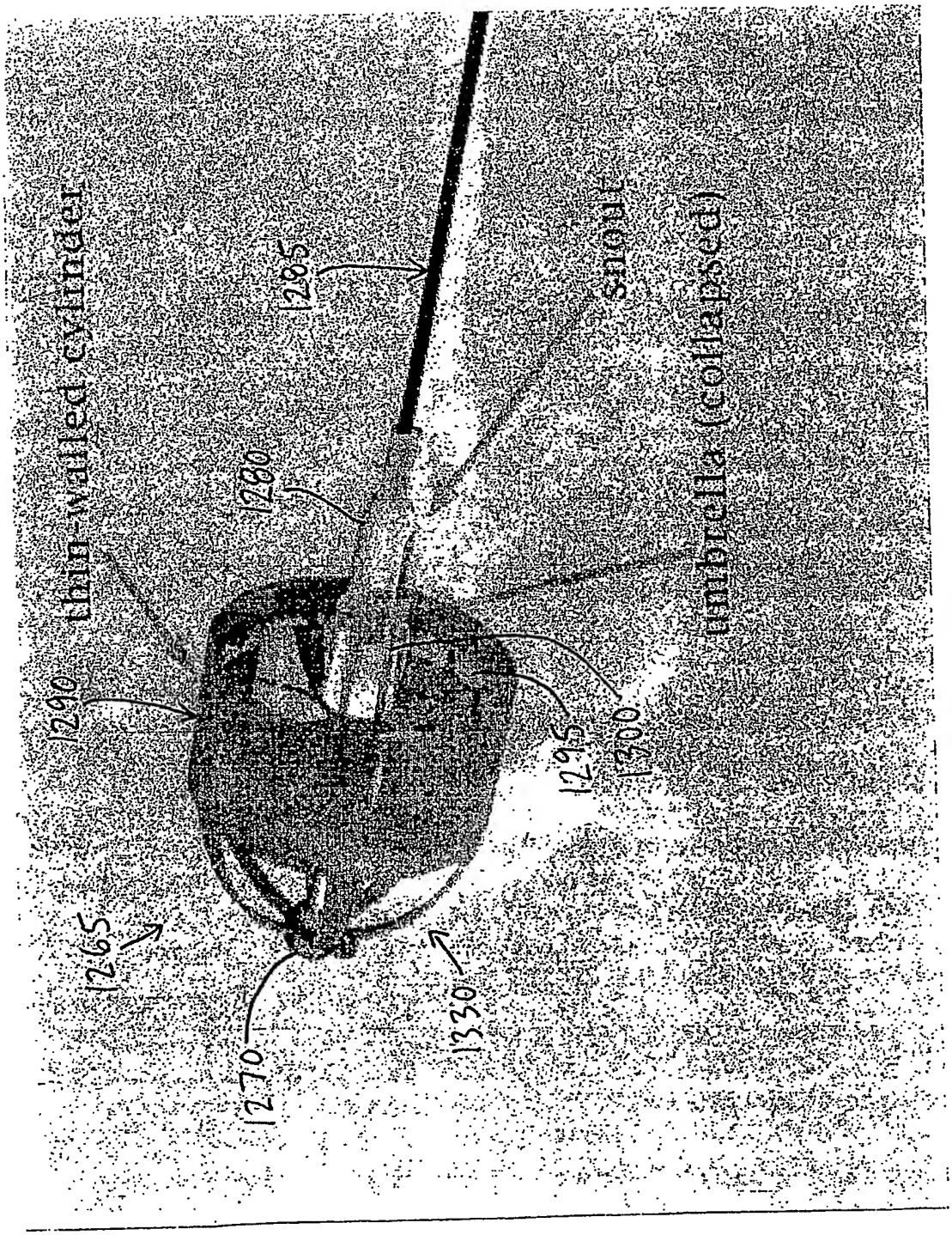
1290 thin-walled cylinder
1265
1280
1295
snout
umbrella (collapsed)
1295
1300
1330
1270
1265

FIG. 93

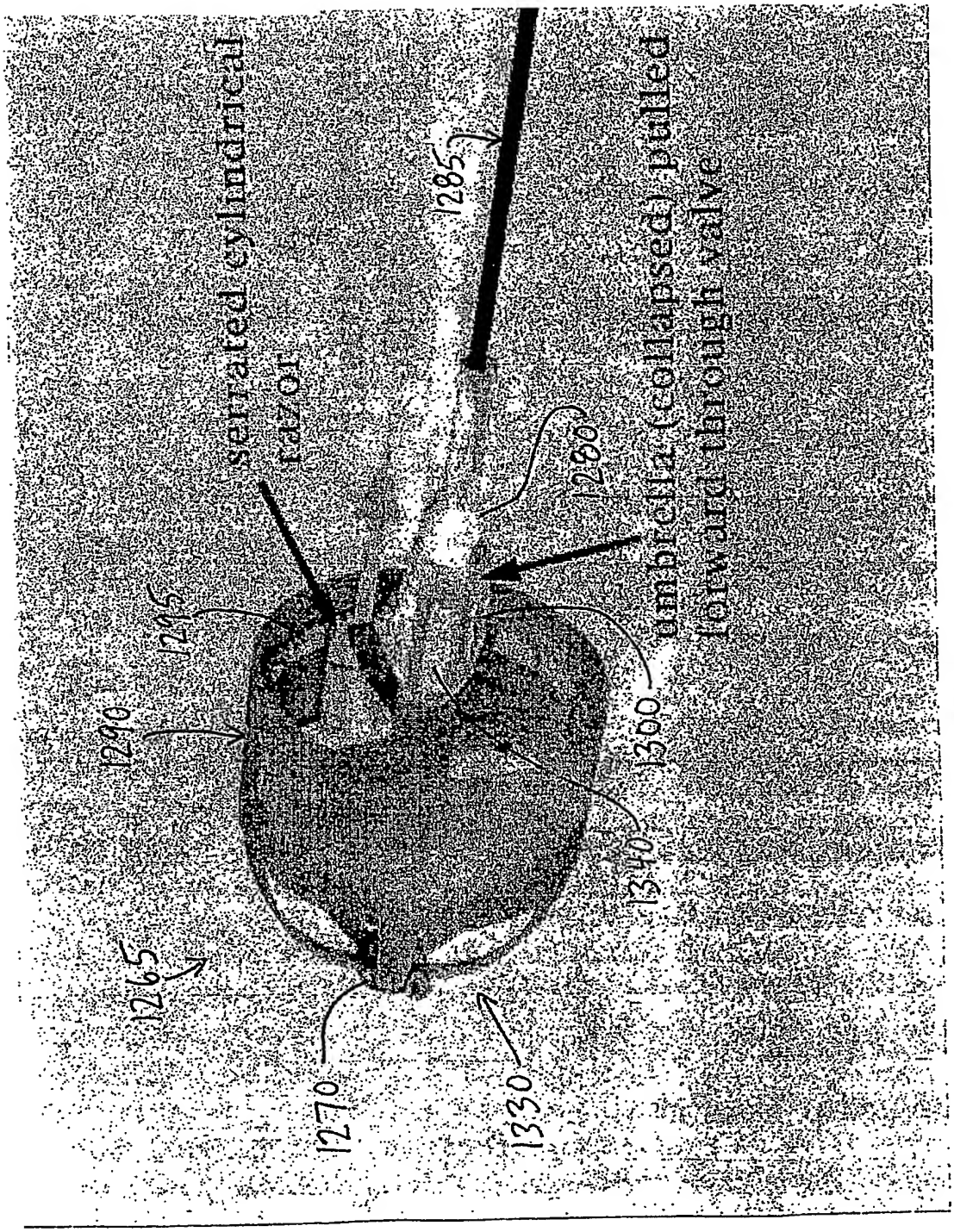
serrated cylindrical
razor
1290
1295
1265
1270
1330
1340
1300
1280
1285
tamper (collapsed) pulled
forward through valve

FIG. 94

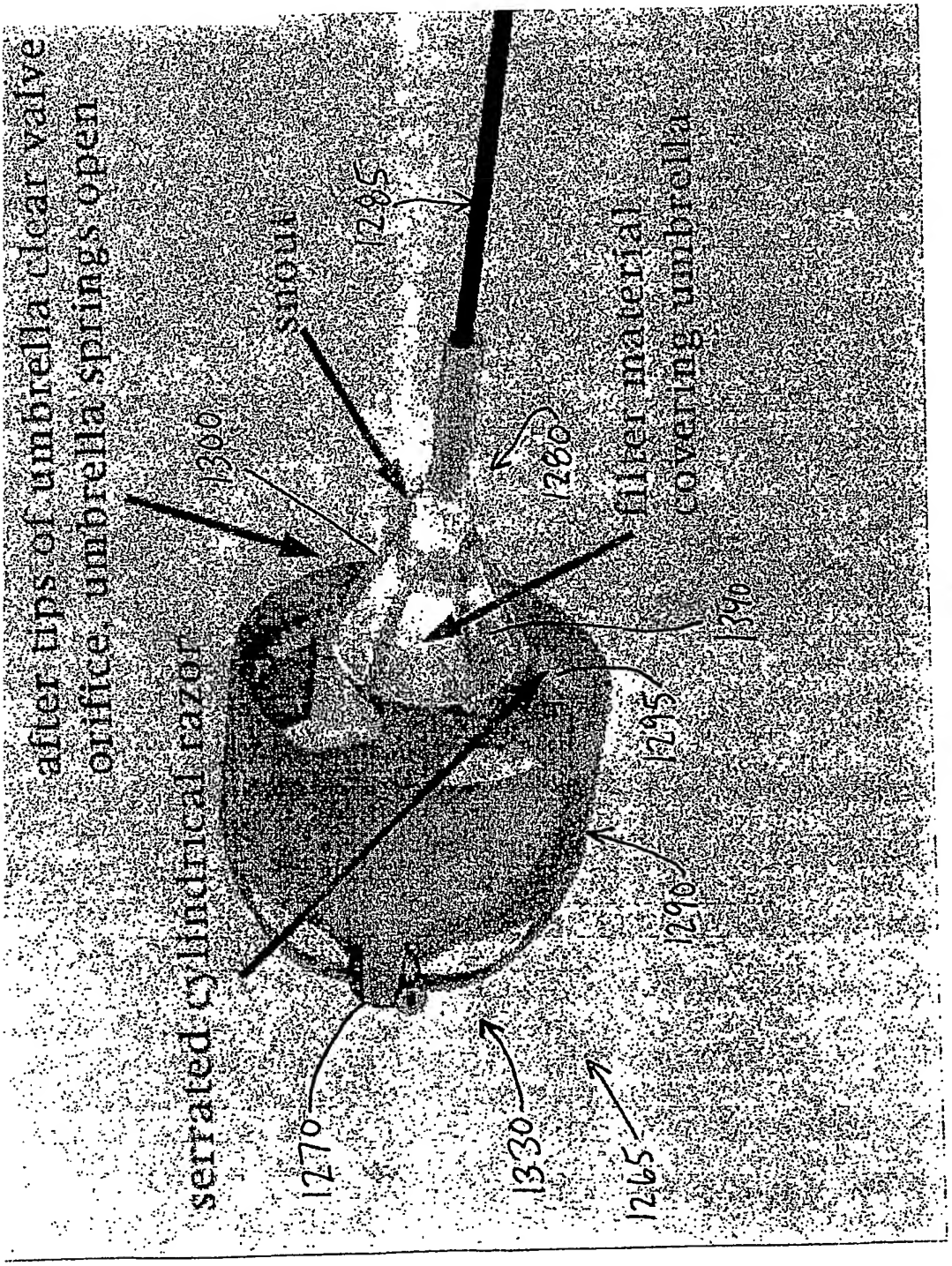
after tips of umbrella clear valve
orifice umbrella springs open
serrated cylindrical razor
1300
suture
1285
1280
filter material
covering umbrella
1290
1295
1270
1330
1245

FIG. 95

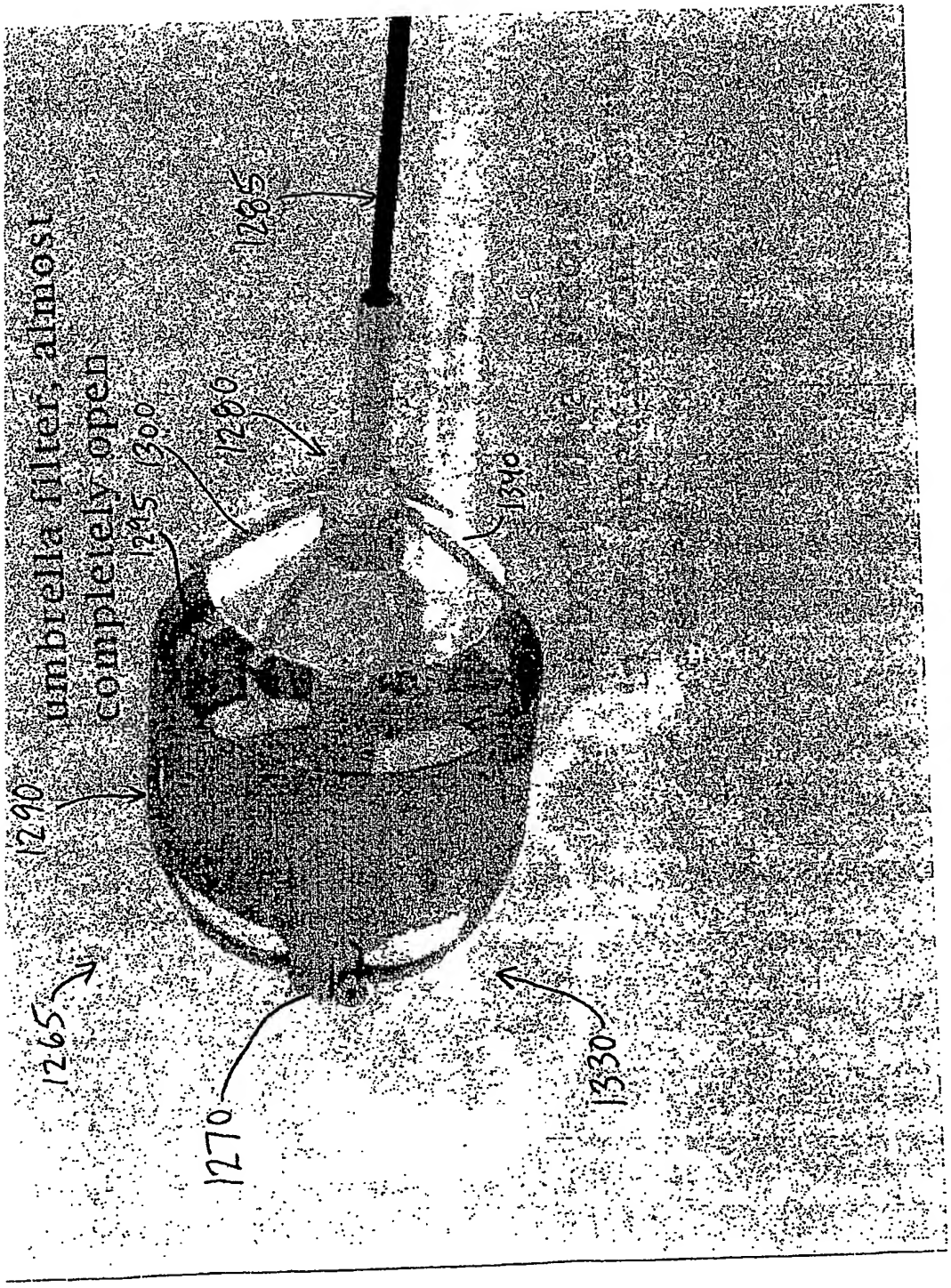
umbrella filter, almost completely open
1200
1265
1270
1265
1300
1280
1285
1340
1330

FIG. 96

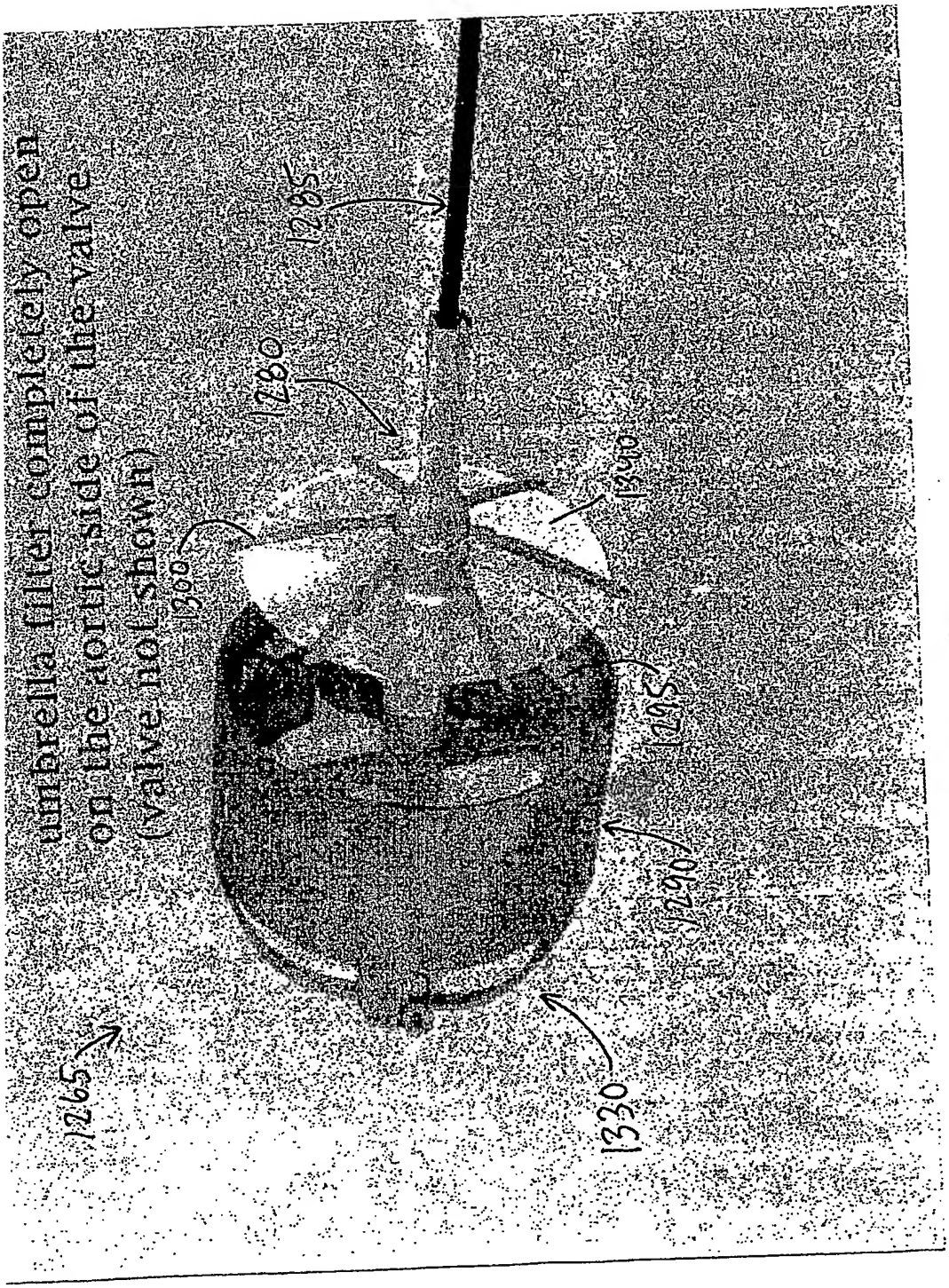
umbrella filter completely open
on the aortic side of the valve
(valve not shown)
1265
1280
1285
1300
1320
1330
1290
1295

FIG. 97

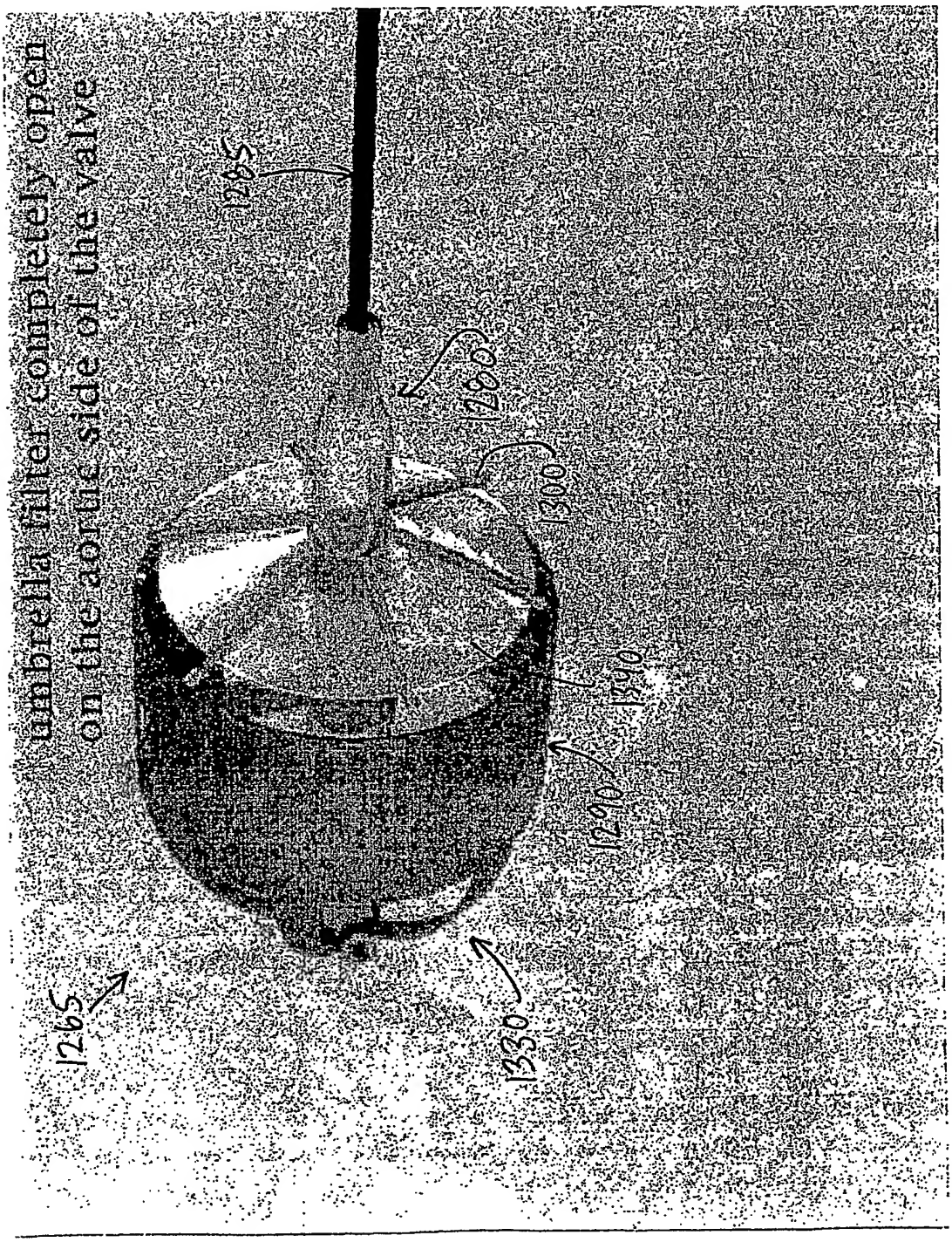
umbrella filter completely open
on the aortic side of the valve
1265
1285
1200
1300
1330
1210
1310

FIG. 9B

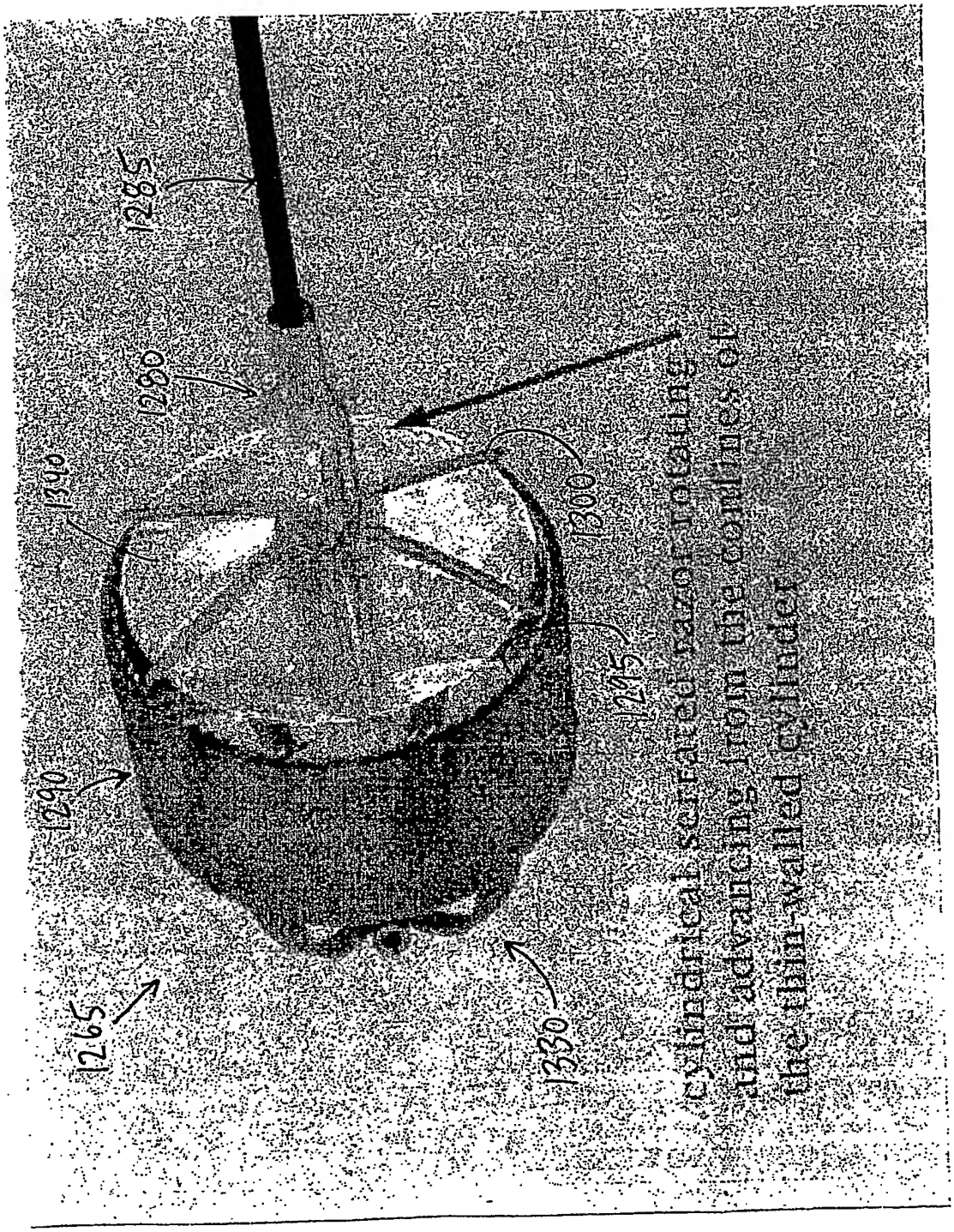
1285
1280
1290
1300
1295
1265
1330
Cylindrical surfaced nozzle protrudes
and advances from the cowling's aft
thin-walled cylinder

FIG. 99

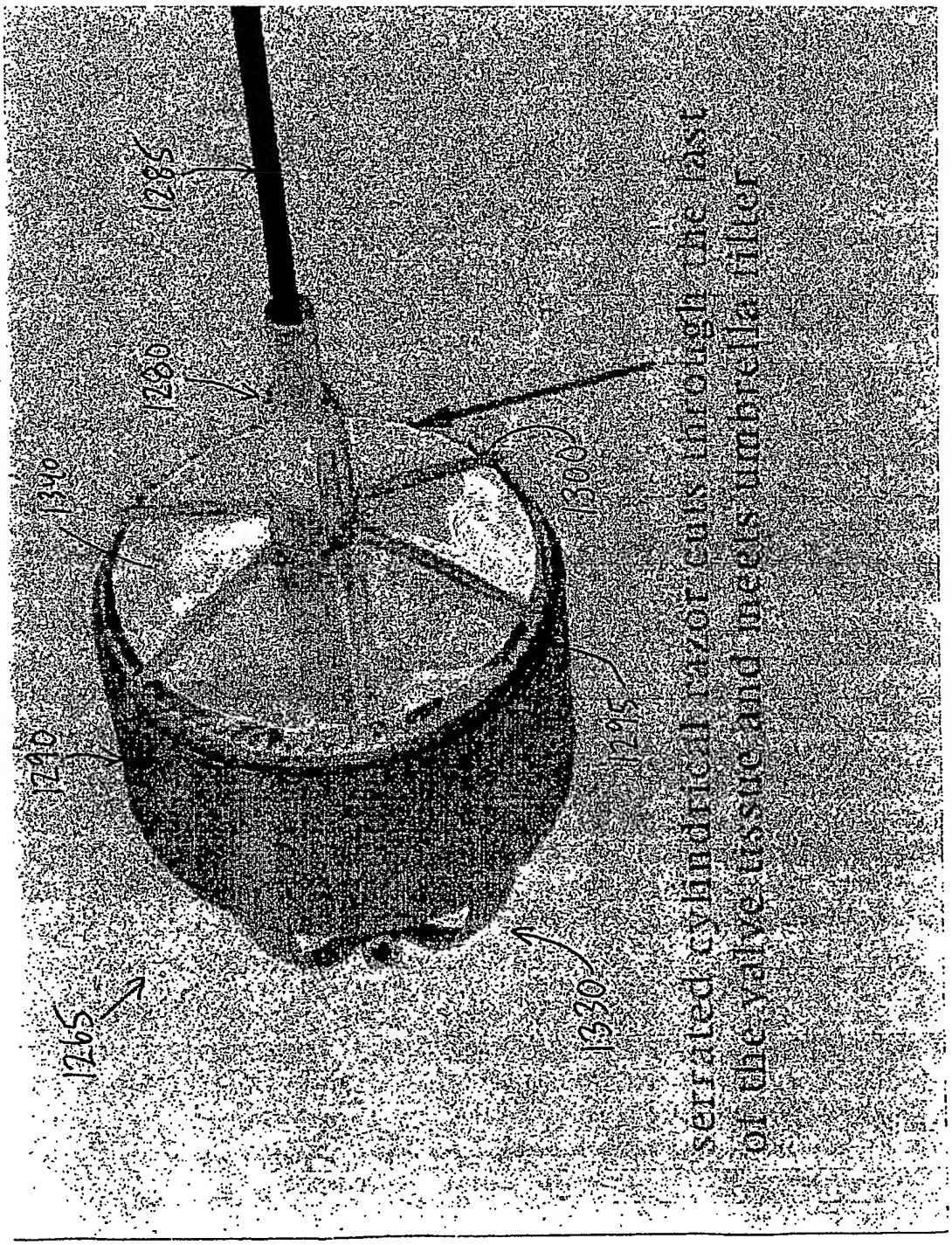
1210
1220
1265
1280
1300
1295
1330
serrated grinding razor cuts through the last
of the valve tissue and peels umbrella filter

FIG. 100

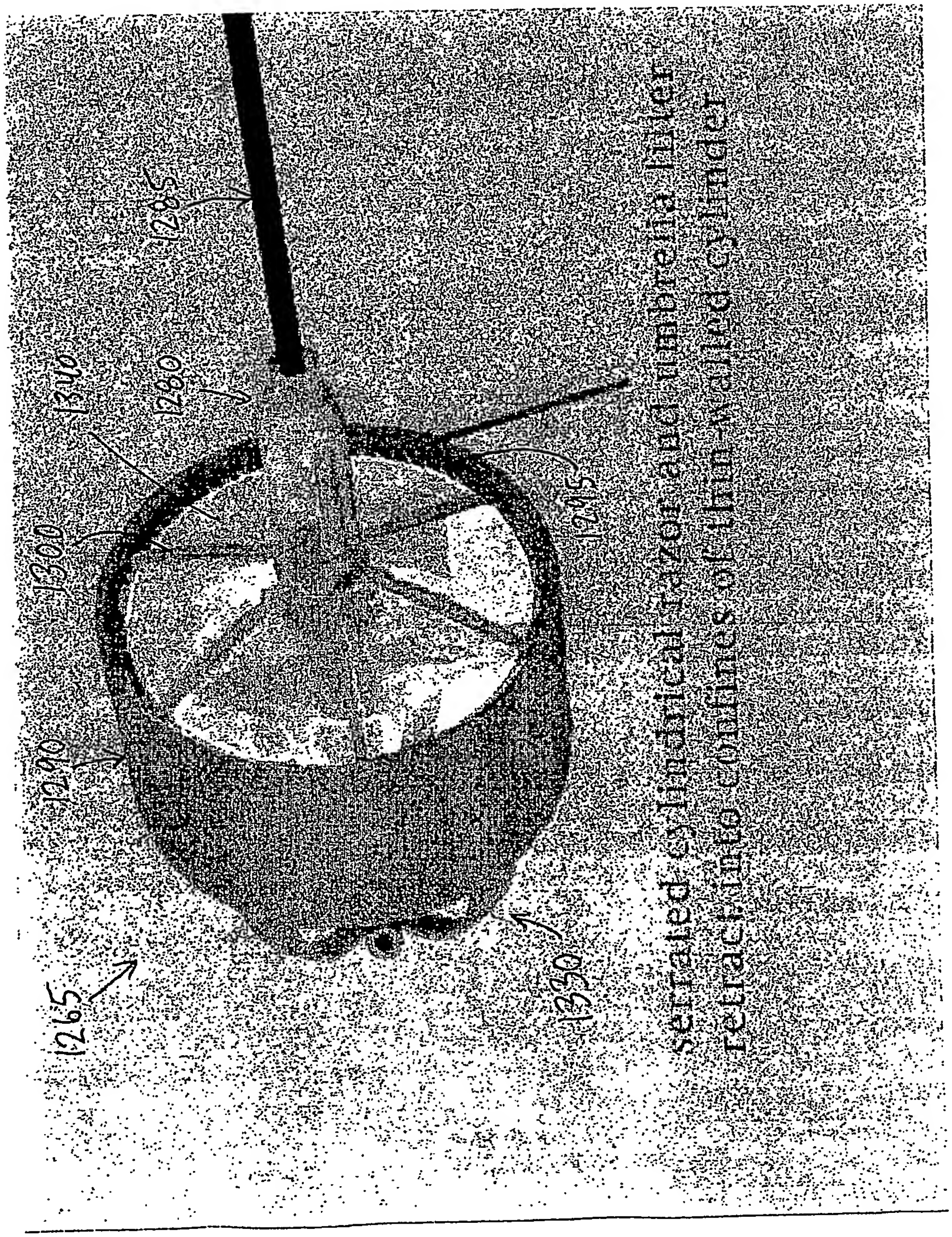
1285
1340
1280
1300
1290
1295
1265
1330
serrated cylindrical razor and umbrella filter
retract into confines of thin walled cylinder

FIG. 101

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(71) Applicant: VIACOR, INC. [US/US]; 260-B Fordham Road, Wilmington, MA 01887 (US).

(72) Inventors: WOOLFSON, Steven, B.; Constitution Marina, 28, Constitution Road, P.O. Box 51837, Boston, MA 02205 (US). STREETER, Richard, B.; 66 Brookside Avenue, Winchester, MA 01890 (US). TAYLOR, Daniel, C.; 35 Faneuil Street, Brighton, MA 02135 (US). COHN, William, E.; 104 Lagrange Street, Chestnut Hill, MA 02467 (US).

(74) Agent: PANDISCIO, Mark, J.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

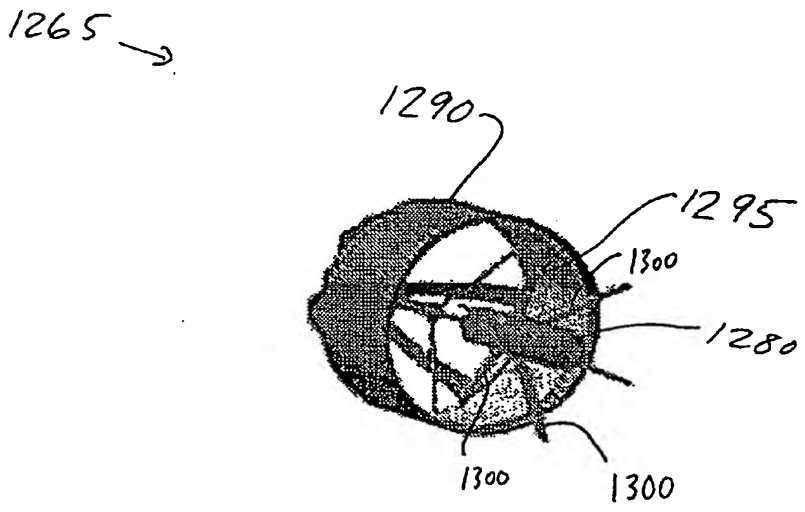
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR RESECTING AND REPLACING AN AORTIC VALVE



(57) Abstract: Apparatus for resecting a diseased heart valve comprising: a body portion having a first end and a second end, a lateral wall, the body portion defining a longitudinal axis from the first end to the second end; a first handle (1270) and a second handle (1280) attached to the body portion; a cutting blade (1295) selectively rotatable about the longitudinal axis; a set of retaining arms (1300); a pass-off tool having a proximal end and a distal end, a first attachment device at the distal end thereof; and a controller tool (1285) having a proximal end and a distal end, a second attachment device at the distal end thereof configured to selectively engage the second handle so as to allow positioning of the second end of the body portion adjacent to disesased heart valve, a cutting blade actuator and a retaining arm actuator.

WO 2003/088809 A3

(88) Date of publication of the international search report:
1 July 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/11532

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 17/32
US CL : 606/170, 184
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/170, 184, 96, 159

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,080,173A (WILLIAMSON ET AL.) 27 JUNE 2000, COL. 4, LINE 8 TO COL. 5, LINE 32.	1-11, 28-30
X	US 6,200,322 B1 (BRANCH ET AL.) 13 MARCH 2001, COL. 7, LINE 12 TO COL. 15, LINE 27	12-18
X	US 5,665,098 A (KELLY ET AL.) 09 SEPTEMBER 1997, COL. 5, LINE 29 TO COL. 7, LINE 50.	19-27, 31-39, 44-53
X	US 5,591,187 A (DEKEL) 07 JANUARY 1997, COL. 4, LINE 15 TO COL. 6, LINE 47.	40-43
X	US 5,843,121 A (YOON) 01 DECEMBER 1998, COL. 4, LINE 37 TO COL. 10, LINE 22.	54-68

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Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
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Alexandria, Virginia 22313-1450
Facsimile No. (703)305-3230

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